

APPLICATION HELP | PUBLIC

SAP Advanced Track and Trace for Pharmaceuticals
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# **SAP Advanced Track and Trace for Pharmaceuticals**

Release 2.0 Feature Pack 3





## **Content**

1	SAP Advanced Track and Trace for Pharmaceuticals	6
1.1	What's New in SAP Advanced Track and Trace for Pharmaceuticals	8
	Overview of Changes for SAP Advanced Track and Trace for Pharmaceuticals 2.0, Feature	
	Package 03	8
	Rules Framework Enhancements	10
	Supply Chain Partner Interaction	11
	Enhancements in ECC & SAP S/4HANA Add-On	11
	SAP Innovation Collaboration Hub (SAP ICH) Adapter	11
	Roundoffs	11
	Enhancements to the Country Version Russia	12
	Enhancements to the Country Version Europe	12
	Integration Component for SAP S/4HANA 1809 FPS01	12
2	SAP Advanced Track and Trace for Pharmaceuticals Data Cockpit	13
2.1	Master Data	16
	Business Partner	17
	Location	21
	Trade Item	23
	System	27
	Creating or Changing Master Data Entities	30
	Master Data Change Logging	31
2.2	Serial Number Management	
	Serialization Profile	34
	Range Definition	38
	Range	43
	Range Request	
	Serial Number	48
	Serial Number Exchange	
	Asynchronous Serial Number Request Response via SAP Information Collaboration Hub	
	Serial Number Status Management and Usage Interface.	
	Additional Functionalities for Advanced Serial Number Management	
	Serial Number Management Data Change Logging	
2.3	Repository Browser.	
0	Lot	
	Serialized Trade Items.	
	Serialized Container.	
	Events	
		07

	Reporting Events	69
	Business Transaction	71
	Authentication Requests	. 75
	Historic hierarchy	77
	Object Tracing and Event Processing	78
	Requesting EPCIS messages	. 94
	Extending the Data Cockpit UI	94
3	Web Applications Along with SAP Advanced Track and Trace for Pharmaceuticals	95
3.1	Web Data Cockpit	96
3.2	Authenticator	97
3.3	Mobile Warehouse	. 97
3.4	Mass Posting	98
4	Country-Specific Features	100
4.1	Argentina	. 100
	Regulatory Reporting Messages when Shipping Goods	. 102
	Regulatory Reporting Messages when Receiving Goods	. 107
	Handle Alerted Shipments on Sender Side	. 108
4.2	China	.109
	China Product Master	. 110
	China Serial Number	111
	Regulatory Reporting for China	. 112
	Scenarios for Specific Drugs in China	. 112
4.3	European Union	113
	Country Package European Union	. 113
4.4	India	127
	Regulatory Reporting for India	. 129
4.5	South Korea	. 138
	Master Template Raw Data Integration with ECC Add-on	. 140
	Regulatory Reporting for South Korea	141
4.6	Turkey	. 145
	Regulatory Reporting to ITS	145
	Data Exchange with PTS	. 146
4.7	United States of America	. 146
	Lot DSCSA	148
	Item DSCSA	151
4.8	Russia	. 152
5	Deployment Models	155
5.1	Mixed Deployment	157
5.2	Distributed Deployment.	. 157

	Replication of Customizing
	Replication of Master Data
	Replication of Transactional Data
	Deployment of Central and Local Instances
	Queue Mechanism for Replication
6	SAP S/4HANA and SAP ECC Add-on for SAP Advanced Track and Trace for
	Pharmaceuticals
6.1	Master Data Maintenance and Integration
	Integration of Customers and Vendor as Business Partners
	Integration of Plants and Storage Locations as Locations
	Enhancement of Material Maintenance
6.2	Transactional Data Integration
	Integration of Production Orders, Process Orders, Purchase Order, Inbound Deliveries, Outbound Deliveries and Return Deliveries
	Batch Enhancements and Integration
6.3	Warehouse Integration
0.5	Warehouse Toolbox Activities
6.4	Enriched Advanced Shipping Notification (eASN)
0.4	eASN Handling During Outbound Processing
	eASN Handling During Inbound Processing
	5. 5
7	EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals
7.1	Master Data Integration and Enhancement
7.2	Transactional Data Integration And Enhancement
7.3	Warehouse Integration with Warehouse Toolbox and SAP Advanced Track and Trace for
	Pharmaceuticals functions
8	Operations Information
8.1	Archiving of Data
	Archiving Object Data
	Archiving Event Data
	Archiving Business Transaction Data
	Archiving Reporting Event Data
	Archiving Serial Number Data
	Storage in ILM System
	Archive Destruction using ILM System
	Destruction of Object Data
8.2	Integration of External Systems
8.3	Usage of AIF Error Handling and Alerting for SAP Advanced Track and Trace for Pharmaceuticals
	Customizing of AIF Error Handling and Alerting in SAP Advanced Track and Trace for
	Pharmaceuticals

Customer Specific Setup of Error Handling/Alerting	. 212
Usage of the AIF Interface Monitor	. 215

## 1 SAP Advanced Track and Trace for Pharmaceuticals

#### **Product Information**

Product	SAP Advanced Track and Trace for Pharmaceuticals
Release	2.0 Feature Package 03
Based on	SAP NetWeaver
	SAP Application Interface Framework
	CD Basis
	For the relevant releases, see the installation notes and the Administrator's Guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp
Documentation Published	February 2019

#### Use

SAP Advanced Track and Trace for Pharmaceuticals supports pharmaceutical companies to comply with country-specific legal requirements on serialization, tracking and tracing, and regulatory reporting of pharmaceutical products. In addition, you can use the solution to facilitate data exchange with packaging lines, supply chain partners (for example Third Party Logistics (3PL), Contract Manufacturing Organizations (CMO)) and warehouse applications.

#### **Features**

- Report serial number events to authorities and business partners, enabling compliance to international legislation
- Integrate with ERP, warehouse management systems and packaging lines
- Capture serial numbers from packaging lines and warehouse systems and store serial number events
  centrally.
- Track and Trace serial number of medicinal sales units and their aggregations
- Track batches and their serial number relation
- Globally manage number ranges and randomized or sequential serial number lists

- Browse and effect internal reporting on the usage and distribution of serial numbers globally
- Authenticate batches and serialized trade items

The solution also supports country-specific legislations which give special requirements on serial number management with definition (length, character set), randomization, data capturing, data exchange with supply chain partners, reporting, and uniqueness.

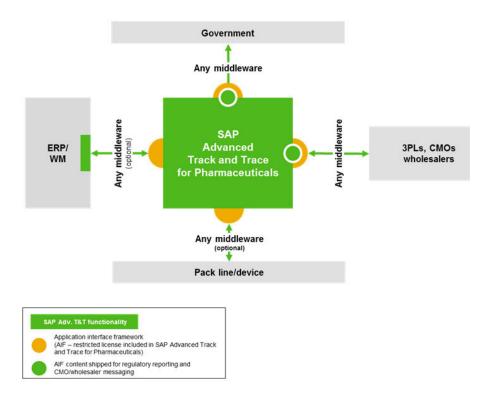
#### **Implementation Considerations**

SAP Advanced Track and Trace for Pharmaceuticals is based on SAP NetWeaver and SAP Application Interface Framework technologies. You can implement SAP Advanced Track and Trace for Pharmaceuticals as a standalone solution on any SAP NetWeaver system.

Optionally, you can implement the ECC Add-On for SAP Advanced track and Trace, based on SAP ERP. The ECC Add-On handles master data integration, transactional data integration and WM warehouse integration. For more information, see ECC Add-on for SAP Advanced Track and Trace for Pharmaceuticals [page 169] in this document.

For more information on how to install, configure, and use SAP Advanced Track and Trace for Pharmaceuticals, see SAP Help Portal at http://help.sap.com/attp.

The following figure illustrates the technical architecture of SAP Advanced Track and Trace for Pharmaceuticals.



## 1.1 What's New in SAP Advanced Track and Trace for Pharmaceuticals

The following sections provide an overview of changes and new features that are available with SAP Advanced Track and Trace for Pharmaceuticals 2.0, Feature Package 03.

Here you can see the overview of the changes:

Overview of Changes for SAP Advanced Track and Trace for Pharmaceuticals 2.0, Feature Package 03 [page 8]

#### Major Changes and New Features for Release 2.0, Feature Package 03

- Rules Framework Enhancements [page 10]
- Supply Chain Partner Interaction [page 11]
- Enhancements in ECC & SAP S/4HANA Add-On [page 11]
- SAP Innovation Collaboration Hub (SAP ICH) Adapter [page 11]
- Roundoffs [page 11]
- Enhancements to the Country Version Russia [page 12]
- Enhancements to the Country Version Europe [page 12]
- Integration Component for SAP S/4HANA 1809 FPS01 [page 12]

## 1.1.1 Overview of Changes for SAP Advanced Track and Trace for Pharmaceuticals 2.0, Feature Package 03

The following table provides an overview of the features delivered with FP03. In addition, the changes to the solution can also be adjustments to the standard behavior delivered via an SAP Note. To have a comprehensive overview, both the information provided here and the SAP Notes should be considered. The detailed technical changes can be found within the release details of the feature package.

Area	Feature
China	Support non-specific resCodes
China	Support 6-digit resCodes
ECC, SAP S/4HANA	Search help on ECC for serialization attributes, such as GTIN, Profile Relevant Country, National Code
ECC, SAP S/4HANA	Configuration table for including custom order types into the standard integration

Area	Feature
ECC, SAP S/4HANA	Aggregation accuracy testing for complete hierarchies
ECC, SAP S/4HANA	Functionality to verify an absolute or percentage-based number of children against a parent object
ECC, SAP S/4HANA	SAP S/4HANA 1809 FPS01 out-of-the-box integration
Encoding/Decoding	Enhanced GCP/National Prefix handling
Encoding/Decoding	Configurable readpoint check
Encoding/Decoding	New encoding/decoding of NTINs as defined by GS1
Encoding/Decoding	Support non-unique Company Registrations and Alternative Location Identifiers
EU	EMVO Release 1.4 – Interface versioning concept
EU	EMVO Release 1.4 – Message adjustments
EU	EMVO Release 1.4 – Master data versioning concept
EU	EMVO Release 1.4 – New UI and Message for Product Withdrawal
EU	EMVO Release 1.4 – Extend Master Data Single Reporting UI
EU	Check Product Pack Data response status before sending Product Pack Update Notification
EU	Remove base UoM dependency
EU	Retrospective reporting based on GTIN and batch for single and multi-market products
EU	Owner GLN on GTIN level to differentiate at reporting
EU	Batch Recall Notification transaction rework
Fiori	Fiori UIs for Mass Processing
Fiori	Fiori UI enhancement for Master Data display
India	Changes to India Reporting to support Batch Details Reporting
Rules Framework	Business Rule to decommission batches including the complete hierarchy
Rules Framework	Business Rule to ship complete batches

Area	Feature
Rules Framework	Retrigger Rules Framework
Rules Framework	Dispositions added to rules framework to further refine the correct rule determination
Rules Framework	Default implementations for customer conditions delivered for target GLN based rule determination
Russia	Standardized mappings for reporting values from specific extension fields
Russia	BAdl enhancements for automated rules processing
SAP Information Collaboration Hub	Communication Adapter for Supply Chain Partner Notification and asynchronous Serial Number Request/Response
Serial Number Management	Add system name for AIF grouping of Serial Number Request
Serial Number Management	Handling and validation of Serial Numbers against Business Partner hierarchies
Serial Number Management	Range Request Automation
Supply Chain Partner Interaction	Ability to send decommissioning events to a supply chain partner, based on the /STTP/CREATE_EPCIS report
Supply Chain Partner Interaction	Callback service for postings through asynchronous EPCIS WebService
Serial Number Management	Extend Serialization Profile determination to check against the Unit of Measure

## 1.1.2 Rules Framework Enhancements

The enhancements are as follows:

- Dispositions added to rules framework
  - You can use these dispositions to further refine the correct rule determination.
- Default implementations for conditions
  - o You can now use default implementations of conditions for rule determination based on target GLNs.
- Re-trigger Rules Framework
  - $\circ$   $\;$  You can re-trigger the rules framework based on existing events within the Cockpit.

## 1.1.3 Supply Chain Partner Interaction

You can now do the following:

- Send decommissioning events to a supply chain partner
  - You can send decommissioning events to a supply chain partner using the /STTP/CREATE\_EPCIS report.
- You can ship complete batches using a business rule.
- You can use a callback service for event postings sent via asynchronous EPCIS WebService.

#### 1.1.4 Enhancements in ECC & SAP S/4HANA Add-On

The enhancements are as follows:

- Search help in ERP Central Component (ECC) for serialization attributes
  - You can use the value help to search for serialization attributes such as GTIN, Profile Relevant Country, National Code, in the ERP Central Component (ECC).
- Configuration table
  - o You can use the configuration table for including custom order types into the standard integration.
- Aggregation accuracy testing
  - You can use aggregation accuracy testing to validate the completeness of hierarchies.
- Verifying number of child objects
  - You can verify the absolute number of child objects or the percentage of child objects against the packratio of a parent object.

## 1.1.5 SAP Innovation Collaboration Hub (SAP ICH) Adapter

The features are as follows:

- You can use the communication adapter for supply chain partner notification.
- You can use the asynchronous serial number request or response.

#### 1.1.6 Roundoffs

The enhancements are as follows:

- New encoding/decoding of National Trade Item Number(NTINs) as defined by GS1
- Enhanced GCP/National Prefix handling
- Business Rule to decommission batches including the complete hierarchy
- Owner GLN on GTIN level to differentiate at reporting and to have default destination for CMO scenarios

• New SAP Fiori UI for Mass Processing

## 1.1.7 Enhancements to the Country Version Russia

The enhancements are as follows:

- BAdl enhancements for automated rules processing
- Standardized mappings
  - You have standardized mappings for reporting values from specific extension fields.

## 1.1.8 Enhancements to the Country Version Europe

The enhancements are as follows:

- Retrospective reporting
  - o You can use retrospective reporting based on GTIN and batch for single and multi-market products.
- Response Status Check for product pack state update notification
  - You can trigger a response status check for product pack state update notification.
- Support of European Medicines Verification Organisation (EMVO) Release 1.4. You can use the following:
  - Interface versioning concept
  - Message adjustments
  - o Master data versioning concept
  - New message for product withdrawal
  - Ul extension for master data reporting to support withdrawal, modification and product versions

## 1.1.9 Integration Component for SAP S/4HANA 1809 FPS01

For SAP S/4HANA 1809 FPS01, you can have master data integration, transactional data integration and warehouse integration from SAP S/4HANA to SAP Advanced Track and Trace for Pharmaceuticals without having to install the add-on. The integration works out of the box.

## 2 SAP Advanced Track and Trace for Pharmaceuticals Data Cockpit

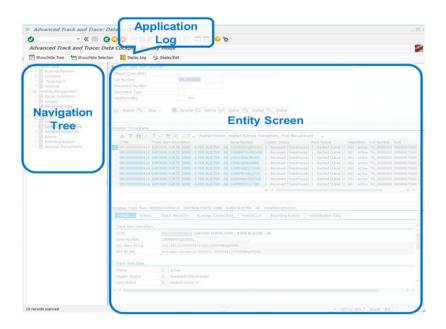
#### **Definition**

With the SAP Advanced Track and Trace for Pharmaceuticals Data Cockpit, you can search, display, and manipulate all the solution relevant entities under **Master Data**, **Serial Number Management** and **Repository Browser**. In one view, the cockpit offers the possibility of context-based navigation. In other words, you can easily navigate from one entity screen to another related entity screen.

#### **Structure**

You can access the cockpit by navigating to SAP User Menu Advanced Track and Trace Repository Data Management Advanced Track and Trace Data Cockpit Alternatively, you can use transaction /STTP/COCKPIT.

**Elements of the Data Cockpit** 



#### Data Cockpit

The main areas of the Data Cockpit are the navigation tree, the entity screen and the application log popup.

#### **Navigation Tree**

From the navigation tree you can navigate to the different entity screens.

#### **Entity Screen**

The entity screen enables search, display and maintenance of all entities.

#### **Application Log**

The log is displayed in a popup. It lists all messages that have been issued by the backend system and logs the findings detected by the backend system or the solution screens and posts it to the application log. It shows the successfully executed actions and errors if any.

#### i Note

Another independent transaction is available in this solution, called as Application Log. Only the Administrator is authorized to use this transaction. For more information, refer to the Application Log.

#### Actions in the Data Cockpit

• Show/Hide Tree: The left pane on the cockpit screen displays the navigation tree. You can choose to show or hide this navigation tree.

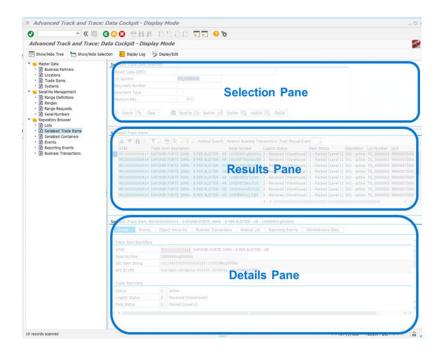
- Show/Hide Selection: Use this option to show or hide the selection pane.
- Display Log: Use this button to launch the popup with the application log display.

Display/Edit: Use this button to toggle between display mode and edit mode of the cockpit.

#### i Note

You can edit the attributes of only one entity at a time.

#### **Elements of the Entity Screen**



#### Entity screen

Each entity screen is divided into three sections – selection pane, results pane, and details pane.

#### i Note

The Serial Number entity screen has only two sections – selection pane and results pane.

#### **Selection Pane**

This pane displays various parameter fields of the entity and helps you search for the required item.

- Search: Use this to search for all possible results based on the values specified in the selection parameters.
- Clear: Use this to clear the values from all the selection fields.
- Add Selection: Use this to add more selection parameters to the selection pane.

- Delete Selection: Use this to remove selection parameters from the selection pane.
- Save Variant: Use this to save a parameter selection as a variant. This helps you to avoid recreating the selection variant.
- Get Variant: Saved variants are available for selection in this catalog even after you exit and re-enter the cockpit.
- Delete Variant: Use this to delete a saved variant.

#### **Results Pane**

When you specify a value for any of the parameters in the selection pane, this list displays a set of results which fit the specified value. This is a standard ALV screen where you can create, sort, print, export and so on. In addition, each entity screen offers specific options to create and delete attributes and even change the status of an attribute.

#### **Details Pane**

This pane displays the details of the item selected in the result list. Apart from the Details and Administrative tabs, this pane includes various inter-related tabs. The tabs vary based on the entity you are working in. However, you need not go to the navigation tree to navigate to other entities. The inter-related tabs in each entity allow you to navigate to other related entities. For more detailed information on each tab of the details pane, see the individual entity topics.

#### More Information

Master Data [page 16]

Serial Number Management [page 32]

Repository Browser [page 61]

#### 2.1 Master Data

#### **Definition**

Typically, master data is maintained in an external system and is then integrated with SAP Advanced Track and Trace for Pharmaceuticals system. However, this solution also allows you to locally maintain the master data objects.

#### Use

This section lists all the master data objects of SAP Advanced Track and Trace for Pharmaceuticals:

- Business Partner [page 17]
- Location [page 21]

- Trade Item [page 23]
- System [page 27]

#### 2.1.1 Business Partner

#### Use

Business Partners are any trading partners with whom traceability data is being exchanged, for example, a CMO (contract manufacturing organization), CPO (contract packaging organization), wholesaler, Third-party Logistics (3PL) company.

Business Partners in SAP Advanced Track and Trace for Pharmaceuticals can have multiple roles reflecting the different business processes a partner participates. In SAP ECC, there are separate master data objects for these roles. For example, there is a customer for sales processes and a vendor for purchasing processes although physically this is the same organization having these roles with same physical attributes like Global Location Number (GLN).

When the Business Partner is integrated to SAP Advanced Track and Trace for Pharmaceuticals, the system checks whether the business partner already exists in this system. The system uses the GLN to check the existence of the Business Partner. If the Business Partner is found, the system adds a new role to the existing business partner. If not, the system creates a new business partner with a new role. However, every role can be assigned only once for a business partner.

When creating a Business Partner Role, it is mandatory to provide the *Role Type* and a *Role Number*. The *Business Partner Role Type* describes the type of the business partner role (for example, vendor or customer). The *Business Partner Role Number* identifies the role and typically reflects the externally known ID such as Customer number or Vendor number. One business partner role can have different externally known identifiers in different source systems. For each different external identifier, a new role variant is created.

In the Data Cockpit search result list (results pane), one line is displayed per role variant. In case a business partner has, for example, three roles and per role, it has two variants, then for this business partner six lines will be displayed. However all tabs of the details pane mostly refer to the business partner as a whole. So irrespective of which line belonging to one business partner number is selected, mostly the same content is displayed in the details pane. If data is changed, these changes are done for the business partner as a whole and not for a particular role variant.

A business partner can have a parent business partner, and with this a business partner hierarchy can be modeled. Currently the business partner hierarchy is not (yet) displayed as a hierarchy in the search result list of the data cockpit. If needed ,the parent business partner can be displayed in the list via the standard ALV option *Change Layout*. A parent business partner can be set to status *Obsolete* only if all child business partners have status *Obsolete* as well. Currently, business partner hierarchies can be maintained locally in the solution only. It is not possible to integrate business partner hierarchies.

#### i Note

Business partner representing the own organization have to be modeled as business partner with role type own organization.

#### **Features**

Given below are the important attributes of a Business Partner:

- **Business Partner Number**: The business partner number is the unique identifier of a business partner within Advanced Track and Trace. This number is generated from an internal number range at creation and has no reference to externally known IDs of Business Partners.
- Business Partner Role Type: This describes the type of the business partner role (for example, Customer, Vendor/Supplier, Contract Manufacturer, Logistic Provider, Own Organization). It is mandatory to choose a type for every role added to a business partner.
- Business Partner Role Number: This is the external identifier of a business partner role and typically reflects the externally known ID of the role such as Customer number or Vendor number. It is unique only in the context of Business Partner Type and Logical System Group.
- **Business Partner Role Variant**: If a business partner has different external identifiers (Business Partner Role Number) for the same role, then, for every external identifier a new role variant is created.
- **Business Partner Status**: describes the current status of the Business Partner. The following values are supported:
  - o Created
  - Active
  - Obsolete
     You can use business partners actively in processes only if they are in active status. You cannot use business partners actively anymore if they are in obsolete status.
- Global Location Number (GLN): The global location number assigned to a business partner is used as an additional external identifier of the business partner. Typically, the GLN is used within EPCIS messages to identify physical locations (typically read point, business location, event source destination: source or destination location) and legal entities (business partners; typically event source destination: source or destination owning party). As the GLN assignment may change over time, historic GLN assignments are stored as well. When a GLN is assigned to a business partner, a formal check is executed to see whether the check digit is correct. The function *Check GLNs* does further consistency checks. Please regularly execute this function and resolve all errors that are reported.
- Parent Business Partner: Add the parent business partner in case of a business partner hierarchy.
- Supply Chain Notification
  - Supply Chain Notification Profile: Select one of the available profiles if you want this business partner to get an EPCIS message when shipping out goods. Supply Chain Notification Profile allows flexible control the content of the supply chain notification being sent to a specific business partner. The maintenance of Supply Chain Notification Profile can be accessed via Customizing ▶ SAP Advanced Track and Trace ▶ Repository Customizing ▶ Reporting Customizing ▶ Supply Chain Partner Notification Customizing ▶ Transaction /STTP/C\_NOT\_PRFL Define Supply Chain Notification Profile Settings ▶. In addition to this setting, you need to configure a rule with rule type SR\_INFORM\_SUCC (Supply Chain Partner: Inform Successor). For more information, see the Customizing documentation in the system: ▶ SAP Advanced Track and Trace ▶ Rule Customizing ▶.
  - Supply Chain Notification System: This parameter is mandatory only if you specify the Supply Chain Notification Profile. You need to add the system to which the EPCIS message has to be sent. Ensure this system has the connection parameters like communication type "web service call" and logical port maintained accordingly. For more information, see System [page 27].
  - Send EPCIS Asynchronous Response: This parameter is used to manage the sending of an EPCIS
    asynchronous response. If an EPCIS message is processed and the sender GLN is assigned to the

current business partner, it's possible to send asynchronous response about the EPCIS processing. If you set this parameter to 'on', the system sends responses. If you set it as 'off', the system doesn't send responses.

• Address: Describes the address of the Business Partner. If the Business Partner is integrated from SAP ECC or an external system, even this data is integrated.

#### • Company Prefix & SSCC Serialization

- o This tab in the details pane contains a table with all global company prefixes (GCPs) which are owned by the business partner. GCPs can be added and removed here with actions *Assign* or *Unassign*. When a GCP is unassigned from a business partner, then the GCP is not deleted it is only unassigned from this business partner and still exists. If needed, the GCP now can be reassigned to this business partner or another business partner. The final deletion of a GCP is also possible via the transaction / STTP/GCP DELETE, which executes comprehensive checks prior to deletion.
- In case Serial Number Management for Serialized Shipping Container Code (SSCC) is done for a
  particular GCP, then additionally you will have to maintain the Serialization Profile and Range Definition
  for every GCP. For detailed information, see Serialization Profile [page 34] and Range Definition [page
  38]. When a range definition is assigned to a GCP of an active business partner, then from that
  moment on only this range definition may be used with the GCP, and no other.
- Assigned Plants: This tab in the details pane displays all the plant locations to which this Business Partner is assigned to; in other words, the plants listed here belong to the business partner. To modify this assignment, double-click on the plant in the *Details* tab to navigate to the *Locations* entity screen of this plant. In this screen you now can assign a different business partner to this plant if wished. For more information, see Location [page 21].
- Assigned Systems: This tab displays all the systems that are assigned to this Business Partner; in other words, the systems listed here belong to the business partner. To modify the system assignment, double click on the system in the *Details* tab to navigate to the *System* entity screen. In this screen, you can assign a different business partner to this system. For more information, see System [page 27].
- **Company Registrations**: This tab displays alternative company registrations or identifiers used in certain specific scenarios.

#### Example scenarios:

- For U.S. data exchange, you can maintain the state licenses here and if maintained they are also exchanged with other supply chain partners (for further details, see country-specific features for United States of America [page 146])
- For South Korea regulatory reporting, the company registrations can be used optionally to determine
  the tags supplier registration number or receiver registration number. For further details, see countryspecific features for South Korea [page 138].
- Besides the usage in legal reporting, company registrations can be used during EPCIS inbound processing as alternative location or business partner identifiers. Instead of providing GLNs or SGLNs for tags like read point, business location, event source destination locations, or owning parties, alternative identifiers can also be used during inbound processing. The used alternative identifiers must be defined at the business partner and location. In addition, for the particular registration type, the prefix used within the message to identify the type must be maintained. The corresponding business partner or location must have a GLN/SGLN assigned, and if an alternative identifier is used within an EPCIS message, the corresponding GLN/SGLN is determined from the business partner / location and used for data creation. So internally the solution works based on GLNs and SGLNs but altenative identifiers can be used in EPCIS messages.

**Example**: A supply chain partner does not send EPCIS messages with GLNs, but uses DEA numbers instead. You need to maintain a business partner / location in your system and assign the GLN/SGLN that will be used for data processing. Besides this, you define a registration type in customizing (for example, **DEA**) and assign the prefix that will be used for data processing (for example, **DEA**). Then,

you define the registration by using the created registration type **DEA** and entering the registration number (for example, **xx000007**), together with all other mandatory attributes (see below). As soon as the registration is valid, it can be used to receive and process EPCIS messages using these alternative identifiers (for example, a read point containing the content **DEA: xx000007** instead of the SGLN in EPC URI format).

You can display, change or delete company registrations.

• Registration type (mandatory): Enter a valid type or select using the value help.

#### i Note

Registration types can be defined through customizing transaction  $/STTP/MD\_REGTYPE$  - Company Registration Types

- Registration number (mandatory): This must be unique within a given validity period.
- Valid from (mandatory): Enter the start date of validity of company registration.
- Valid to (optional): Enter the end of validity.
- Time zone (mandatory): Enter the time zone relevant for validity.
- o Country (optional): Choose the country of validity.
- Region (optional): Choose the region of validity.
- Deletion of company registrations is only possible as long as the valid from date is in the future. In case
  the valid from date is over then the entry cannot be deleted anymore but instead the valid to date has
  to be set.
- The same registration number can be reused by another business partner in case the validity period is not overlapping.

#### **Activities**

You can perform the following actions within the results pane

- Create a new Business Partner
- Create a new Business Partner role
- Merge the selected Business Partner roles with another Business Partner
- Delete the selected Business Partner role
- Change the status of existing Business Partner
- Check GLNs assigned to the Business Partners

#### More Information

Integration of Customers and Vendor as Business Partners [page 171]

#### 2.1.2 Location

#### Use

Locations are used to model physical locations used during supply chain processing. In SAP Advanced Track and Trace for Pharmaceuticals, a location typically represents a plant or a storage location but it can also represent other entities such as storage bins or resources. A location can be hierarchical, for example, storage locations belong to plants and so on.

Typically, plants and storage locations from SAP ECC are integrated with Locations in SAP Advanced Track and Trace for Pharmaceuticals. However, you can maintain the locations locally or integrate them from an external system as well.

#### **Features**

Given below are the most important attributes of a Location:

- **Location Number**: External identifier of the location in SAP Advanced Track and Trace for Pharmaceuticals.
- Location Name: Use this field to provide a short description for the Location.
- Location Type: Describes the type of the Location. The following types are available:
  - Plant
  - Storage Location
  - o Storage Area
  - Storage Bin
  - Distribution Center

#### i Note

You can maintain additional Location Types in Customizing at SPRO SAP Advanced Track and Trace for Pharmaceuticals System Parameters Location Types.

- **Status**: This field describes the status of the location. You can use locations actively in processes only if they are in active status. You cannot use locations actively anymore if they are in obsolete status.
- Global Location Number (GLN) and GLN Extension: The global location number and GLN Extension assigned to a location are used as an additional external identifier of the location. Typically the GLN together with the GLN Extension is used within EPCIS messages as part of the read point or business location SGLN and also to encode transactions. As the GLN and extension assignment may change over time, historic GLN assignments are stored as well. The function *Check GLNs* does further consistency checks. Please regularly execute this function and resolve all errors that are reported.
- SGLN: The SGLN is an encoded representation of GLN + GLN Extension in EPC URI format.
- Location Business Partner Number: This field displays the business partner to which this location belongs to. This assignment is needed, for example, during serial number validation at commissioning to find out whether the serial number request was triggered from the same business partner who requested the serial numbers.

A business partner can only be assigned to the top level location of a hierarchy and is inherited to all "child" locations of the hierarchy. Hence, for the lower level hierarchies, the business partner from the top level location is displayed and cannot be changed.

- **Parent Location Number**: Since Locations are displayed in a hierarchy, this field displays the next higher location in the hierarchy.
- Location Address: This tab displays the mailing address of the location.
- Alternative Location Identifiers: This tab displays alternative identifiers that may be used to identify the location, for example, during EPCIS message inbound processing.

Instead of providing GLNs or SGLNs for tags like read point, business location, event source destination locations, or owning parties, alternative identifiers may also be used during inbound processing. The used alternative identifiers must be defined at the business partner and location. In addition, for the particular registration type, the prefix that is used within the message to identify the type must be maintained. The corresponding business partner or location must have a GLN/SGLN assigned. and if an alternative identifier is used within an EPCIS message, the corresponding GLN/SGLN is determined from the business partner / location and used for data creation. So, internally, the solution works based on GLNs and SGLNs, but alternative identifiers can be used in EPCIS messages.

**Example**: A supply chain partner does not send EPCIS messages with GLNs, but uses DEA numbers instead. You need to maintain a business partner/location in your system and assign the GLN/SGLN that shall be used for data processing. Besides this, you define a registration type in Customizing (for example, **DEA**) and assign the prefix that shall be used for data processing (for example, **DEA**). Then, you define the registration by using the created registration type **DEA**, and entering the registration number (for example, **XX000007**) together with all other mandatory attributes (see below). As soon as the registration is valid, it can be used to receive and process EPCIS messages using these alternative identifiers (for example, a read point containing the content **DEA**: **XX000007** instead of the SGLN in EPC URI format).

#### **Activities**

You can perform the following actions within the results pane

- Create a new Location
- Change the status of existing locations
- Check GLNs assigned to the locations

#### More Information

Integration of Plants and Storage Locations as Locations [page 172]

#### 2.1.3 Trade Item

#### Use

A Trade Item keeps all common master data of Serialized Trade Items which are handled in supply chain processing. In SAP Advanced Track and Trace for Pharmaceuticals, Trade Item is identified by the Global Trade Item Number (GTIN).

Trade items are typically integrated from SAP ECC materials but they can also be maintained locally in the SAP advanced Track and Trace for Pharmaceuticals system and one can also integrate Trade Items from other non-SAP ERP systems.

One trade item can have multiple product variants. ERP systems like, for example, SAP ECC typically manage trade items as materials and the GTIN is assigned to one of the alternative UoMs of the material. A business user typically knows the material number better than the GTIN. Therefore the trade item in addition has a material reference to search and display the trade items for a particular material number. Now, the same GTIN may be assigned to two different materials in two different ERP systems, but still represent the same trade item. Whenever such a case happens and the same GTIN is integrated with another material reference, then a new trade item variant is created. So the trade item variant carries a different alternative material assignment for the same trade item (GTIN). With this approach the user can search and display trade items (GTINs) for their externally known material numbers. However the material assignment is really only used for this purpose. Serialized trade items solely use GTINs and there is no relation at all to the material.

Within the data cockpit search result list, for every trade item variant a separate line is displayed. So if a trade item has three material assignments, then it has three variants and three lines are displayed for the same trade item. However the tabs in the details area refer to the trade item as a whole and not to individual variants. The only screen area that reacts on the variant is the section *Variant Data* of the details tab. This means whenever you select a line for a trade item with multiple variants and whenever you do changes in the details area, you are changing the trade item as a whole and not just the variant.

#### **Features**

Given below are the important attributes of a Trade Item:

- **Global Trade Item Number**: GTIN is the primary key of the trade item. This is a 14 digit number which can be used by a company to uniquely identify all of its trade items. A GTIN consists of the Company Prefix, Item Reference and a calculated Check Digit.
- Trade Item Description: Use this field to provide a short description for the Trade Item.
- Trade Item Status: describes the current status of the Trade Item. The following values are supported:
  - Created
  - Active
  - Obsolete

#### i Note

Only Trade Items in active status can be used in active processes like, serial number request or commissioning of SGTINs.

- **Serialization Type**: This denotes if a trade item is relevant for serialization and the degree by which events have to be composed or tracked for this trade item. The following are the serialization types supported:
  - Lot Managed: Trade item is subject to lot level tracking. Only event messages with respect to LGTINs to be received or composed for such trade items.
  - Serialized (Publishing only): Trade item is serialized. The Commissioning are posted to repository and eventually regulatory reporting is triggered for commissioning if relevant. No further events are recorded and stored in repository.
  - Serialized & Traced: Trade item is serialized and all received events are recorded and stored in repository.
- Unit of Measure of Trade Item: This describes the UOM in which the trade item is measured.
- National Trade Item Code and National Trade Item Code Type: This field can be used to maintain the national code and the corresponding code type which is valid for the profile-relevant country. The combination of code and type must be unique.
- Trade Item Registration Code: This field can be used to maintain the registration code of a trade item.
- Profile Relevant Country: The profile-relevant country is a dedicated country within the list of country assignments of a trade item. The profile-relevant country is used both for determination of the serialization profile and also during regulatory reporting as a fallback if the country cannot be determined otherwise. The profile-relevant country can only be maintained on the details tab. It is displayed on the Countries tab but cannot be changed there. For further details, see Serial Number Management for Trade Items [page 261.
- Serial Number Management Type: The indicator *Trade Item Serial Number Management Type* defines whether this trade item is subject to serial number management in SAP Advanced Track and Trace for Pharmaceuticals. The attribute can have the following values:
  - o *Initial*: Not defined/ Not serial number managed: In this case, it is not defined whether serial number management will be done for this trade item. The trade item can be activated with or without a serial number range definition assigned.
  - X: Internal serial number management: In this case, the trade item is subject to internal serial number
    management and a range definition with origin *Internal* will be created. *Internal* indicates that the serial
    numbers and ranges are owned and generated within this system. Activation of the trade item is only
    possible if a range definition with origin *Internal* is assigned to the trade item.
  - E: External serial number management: In this case, the trade item is subject to external serial number management and a range definition with origin External will be created.
     Activation of the trade item is only possible if a range definition with origin External is assigned to the trade item. You have to reference a customer that represents the source of the serial numbers to allow the automated creation of range definitions.
- Business Partner(Customer) to provide Serial Number: In case of serial number management type
  external serial number management, your company, for example, acts as contract manufacturer (CMO)
  for a Marketing Authorization Holder (MAH). Here, you do not generate the serial numbers within your
  system but you request the numbers from the MAH via serial number request. This attribute is to specify
  the business partner (customer), which is your MAH and which provides the serial numbers to you.
- Serialization Profile: Assign the serialization profile that shall be used for serial number management of the trade item. The serialization profile defines how the serial number is composed. For further details, see Serial Number Management for Trade Items [page 26].
- **Product Category**: The Product Category categorizes the product. Its main usage is to control the assignment to the correct range definition in case a serialization profile with uniqueness scope "by product category" is assigned to the trade item.
- Range Definition for Serialization: The Range Definition spans up the potentially available number space that can be used for serial number management of this trade item. In case a range definition is assigned to

- a trade item in status active this means that this trade item is subject to serial number management. For further details, see Serial Number Management for Trade Items [page 26]
- Variant Data: This section in the details tab displays the material variant information Material Number, Product Variant, Base UOM of Material, and Logical System Group and conversion factors between UOM of trade item and base UOM of Material.
- Countries: This tab displays the countries assigned to the trade item. A trade item can have multiple country assignments. This means that the trade item can be traded within all of these countries. Use the actions in this tab to assign or unassign a country to the trade item. However, there can be only one profile relevant country assigned to a trade item. For every country you can assign a national code, a national code type and registration code. The profile-relevant country is displayed on this tab only. Change of profile-relevant country is possible on the details tab.
- **Location Assignments**: This tab displays the locations assigned to the trade item. Use the actions in this tab to assign or unassign a location to the trade item.
- System Assignments: This tab displays all systems that are entitled to request serial numbers for this trade item. Use the actions in this tab to assign or unassign systems. All systems with the check box allow serial number request for all trade items selected are always displayed and cannot be removed.



All changes to trade items, in principle, are logged using change documents. The assignment of the trade item to the system technically is managed at system level. So changes to the assignment done on the trade item UI are not visible on the *Change Documents* tab of the trade item but only for the system. For more information, see Master Data Change Logging [page 31].

• Time Dependent Attributes: This tab allows you to add time dependent key or value attributes. Note:

#### i Note

There is no Customizing foreseen to define the time dependent property keys. SAP defines the keys as domain values to restrict the use cases and to ensure performant processing for the necessary use cases. The only use case supported as of now for time dependent attributes is to handle the assignment of National Code Versions, to a trade item in case of China Material Master Handling. For more details, see Country-specific Features for China [page 109].

Additional Attributes: This tab allows you to add the Property Name or Property Value attributes to the trade item. Property names can be defined in customizing at SPRO SAP Implementation Guide SAP Advanced Track and Trace for Pharmaceuticals System Parameters Product Property Names SAP delivers a set of properties required for Regulatory Reporting for certain countries. You need to maintain these properties for trade items if regulatory reporting for these countries is considered. By using Assign Country-Specific Attributes, you can assign all needed country attributes at once. Based on the assigned countries the relevant attributes are determined and added. In case of Europe, the attributes are only added if at least one country is assigned to the trade item that is relevant for reporting to the European Hub.

#### → Tip

Country relevance for European Hub is maintained in Customizing.

By using *Check Country Reporting Attributes*, you can check whether all attributes have been maintained correctly to ensure a successful regulatory reporting

#### → Tip

In general Customizing, you can define whether this check is executed on the activation of the trade item, and whether check errors are only logged or they block the activation. For more information, see the configuration guide, chapter *General Customizing (ATTP)* for parameter <code>CHECK\_RR\_CNTRY\_MSTR</code> on the SAP Help Portal, at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>).

For more information, see *Regulatory Reporting* and *Supply Chain Reporting* in the topic Outbound Processing [page 89].

#### **Activities**

You can perform the following actions in the results pane:

- Create a new Trade Item Assign attributes
- Check Country Reporting Attributes (see **Additional Attributes** above)
- Change the status of a trade item
- Assign Attributes: You can select multiple trade items and then execute this function and assign certain attributes to all of them. In addition, you can trigger actions such as assign/create SNR range definition or activate trade item by selecting the respective checkboxes.
- Attachments: With this function you can upload attachments to a particular trade item.

Deletion of trade item is not possible within the data cockpit. Under certain conditions trade item versions can be deleted via transaction /STTP/DEL\_TR\_ITM\_VAR. Please refer to the documentation within the transaction to learn about the conditions and restrictions.

#### **More Information**

Enhancement of Material Maintenance [page 173]

## 2.1.3.1 Serial Number Management for Trade Items

#### Use

During the process of Serial Number Management for a Trade Item, a Serialization Profile and a Range Definition have to be assigned to the Trade Item.

#### **Process**

- Serialization Profile: Within the trade item, a serialization profile can be determined automatically using Determine Profile for the maintained profile relevant country. The determination is done differently for the different serial number management types, as follows:
  - For serial number management type <blank> (not defined/not serial number managed) and X
     (internal serial number management), the serialization profile is determined for the maintained profile-relevant country from the serialization profile.
  - For serial number management type *E* (external serial number management) the serialization profile is determined via the combination of business partner and country from the serialization profile. With this, you can define an individual serialization profile for every business partner/country combination, if you are acting as a CMO for an MAH.
  - o If more than one serialization profile is found, the system chooses the profile with the higher priority of country assignment. Alternatively, you can select the value in the field. The field then displays all the serialization profiles relevant for the profile-relevant country (serial number management types <br/> *blank*>and *X*) or for profile-relevant country and business partner (serial number management type *E*). Note that you cannot assign serialization profiles that are not maintained for a particular country (or a business partner to country assignment for *External Serial Number Management Type*)
- Range Definition: After assigning the serialization profile, the range definition has to be added to the trade item. You can use the Assign/Create button. This is to comply with the definition of uniqueness scope in the serialization profile. Based on the uniqueness scope, the system determines whether a new range definition has to be created or an existing one can be reused. Alternatively, you can provide specific values in the appropriate fields to create a new range definition. Basically, every range definition that fits the attributes of the serialization profile can be assigned explicitly.

#### i Note

When you assign a new range definition, you can overrule the logic which is defined by the uniqueness scope of the serialization profile.

After the assignment of the range definition, the trade item is ready for serial number management. In case the serialization profile used for creation of the range definition has a range automation profile assigned then serial number entities are automatically prepared for productive use. Please see Serial Number Management [page 32] (especially Serialization Profile [page 34]) for more information. Trade items without assignment of range definition are not relevant for serial number management. You can use such trade items for data processing only.

## 2.1.4 System

#### Use

Systems are used for all communication with known external systems. Specifically, systems are used for exchange of serial number ranges and serial number lists. In addition, the receiver systems for Regulatory Reporting and Supply Chain communication have to be modeled as a system.

Systems play an important role in serial number management. Systems are assigned to ranges and once assigned they can request either ranges or lists from that range. If the system receives a serial number list, the

system is stored at every serial number provided to the system in order to allow verification later when receiving a commissioning event for this serial number. As this verification is done at the business partner level, it is mandatory for the systems used for serial number management to have a business partner assigned. If the system receives a range, then the system is stored at the range request to verify during commissioning whether the serial number received from the system is within a valid range request.

Please see Outbound Processing [page 89] for further details about Regulatory Reporting and Supply Chain Reporting.

#### i Note

Systems are not integrated from SAP ECC, but are primarily defined within SAP Advanced Track and Trace for Pharmaceuticals only.

#### **Features**

Given below are the important attributes of a System:

- **System Name**: Use this field to specify a name to identify the system.
- **System Description**: Use this field to give a description to the system.
- System Type: Use this field to define the system type. System types are predefined by SAP.

#### i Note

One such system type is Advanced T&T Instance. By selecting it, you declare another system as an SAP Advanced Track and Trace for Pharmaceuticals system within your own distributed system landscape. In a scenario where there is one central system within an SAP Advanced Track and Trace for Pharmaceuticals system landscape and in addition there can be 0 to n local systems. In such a scenario, all the data (customizing, master data, transactional data) is replicated between SAP Advanced Track and Trace for Pharmaceuticals systems within the landscape using RFC calls. When assigning the system type Advanced T&T, the communication type is therefore set to RFC call and the Logical System becomes a mandatory field

- Business Partner of System: The Business Partner of the system specifies to which Business Partner the system is assigned. This typically means that this system is owned by the respective Business Partner. If a system is configured to receive serial numbers, you have to maintain the Business Partner to enable validation later during commissioning of serial numbers. If the Business Partner is not maintained, then commissioning of Serialized Trade Items fails.
- Serial number request parameter:
  - Allow Serial Number Request for all Trade Items: Selecting this check box indicates that the system
    can request serial numbers for all trade items. Alternatively, instead of selecting this check box, the
    allowed trade items can be explicitly added on tab *Allowed Trade Items* and then the system is only
    entitled to request serial numbers for all explicitly added trade items.
  - **Allow SSCC Range Request**: Selecting this check box indicates that the system may request serial numbers for SSCCs.
  - Maximum Serial Numbers per Request: You can define the maximum number of serial numbers that
    this system will receive per request. If the system requests more than the number specified here, then
    the returned number is reduced to the maximum number.

o **Default Outstanding Numbers**: With defining outstanding numbers you can limit the total outstanding serial numbers a system can request. Outstanding numbers are the serial numbers requested by a requesting system for a particular trade item (GTIN) or SSCC (GCP) which are not reported back as commissioned or lost. Default outstanding numbers define the maximum outstanding numbers that will be taken as a default for this system. So this system in total may not have more outstanding serial numbers for a particular GTIN or GCP than defined. If with a serial number request, the maximum outstanding number is reached, the requested quantity is reduced in a way that the maximum outstanding numbers is not exceeded in total. For trade items, the maximum outstanding numbers can be defined at a more granular level per trade item on the tab *Allowed Trade Items*. If no outstanding numbers are defined, then the system may request infinite serial numbers.

#### Communication Settings:

- Communication Type: Use this field to define the kind of communication for data transfer between systems. You can choose either an RFC Call or a Web Service Call. In some cases the communication type is predefined, depending on the type of data exchanged with the system:
  - External systems are typically connected through web service connection
  - Local SAP Advanced Track and Trace for Pharmaceuticals instances always communicate through RFC
  - Systems for Regulatory Reporting are typically maintained with communication type web service. For more information, see Integration of External Systems [page 209].
- Default Communication Mode: You can define whether default communication shall happen synchronously or asynchronously. This parameter is only taken into consideration if not defined within the context.
- External System Name: This is the system name by which your system is known when connected to
  another system. Whenever you need to communicate with the other system, you use the name of this
  external system. The system owner of the other system needs to provide this external system name
  for the two systems to communicate.
- Serial Number Request Type: The solution supports three types of serial number requests. For further details see Serial Number Exchange [page 51].
  - o ATTP 1.0 Synchronous
  - o ATTP 2.0 Synchronous
  - o ATTP 2.0 Asynchronous
- Communication Adapter: Assigning communication adapter to the system will enable all outbound SOAP communication to be processed via an adapter processing logic instead of ATTP logic. You need to implement adapter processing logic in BAdl if you want to use it. You can specify new communication adapter using transaction /STTP/COM\_PRFL and logical port for adapter using transaction /STTP/COM\_PRFLA.
- RFC Settings: Specify the setting only if you have selected the communication type as RFC Call.
  - Logical System: Specify a logical system ID of the connected system.
- Web Service Settings: Specify these settings only if you have selected the communication type as a Web Service Call.
  - **Logical Port**: Specify the logical port of the connected system.
- Allowed Trade Items: In this tab, you maintain all trade items for which the system can request serial numbers. Note that this maintenance is only required if you have not selected the check box Allow Serial Number Request for all Trade Items In addition, for each trade item you can define the maximum outstanding numbers that this system can have for a particular trade item. If not defined here the default outstanding numbers defined on the tab **Details** will be taken for this trade item.

- **Assigned Ranges**: This tab displays the ranges which are currently assigned to the system. The assignment is done in range management. From this tab, you can navigate to the *Range* screen to review the assigned Ranges.
- Authorized GLNs: This tab is currently only relevant for the feature Requesting EPCIS Messages. Here you can maintain the GLN groups for which this particular system is authorized to request EPCIS messages in addition to the standard GLN authorizations derived via the business partner assigned to the system. For more information, see Requesting EPCIS messages [page 94] and the developer guide SAP Advanced Track and Trace for Pharmaceuticals: Requesting EPCIS Messages on the SAP Help Portal at http://help.sap.com/attp.

#### **Activities**

You can perform the following actions in the results pane:

- Create a new System
- Change the status of an existing system

## 2.1.5 Creating or Changing Master Data Entities

#### **Create New Entity**

- 1. Open Advanced Track and Trace Data Cockpit.
- 2. Choose *Display/Edit* in the menu bar to be able to create or edit the attributes.
- 3. Choose Create Master Data and select the required entity. Alternatively, you can select an entity under the Master Data folder of the navigation tree in the Data Cockpit to open the entity screen.
- 4. To create a new entity object, choose the *Create* button in the result pane. In the new entity popup, provide the relevant inputs in all the fields.
- 5. Choose *Confirm* to save the new entity.

#### **Change Attributes**

- 1. To change an attribute, while in the *Edit Mode*, make necessary modifications to the required attribute fields in the detail pane.
- 2. Choose Save in the tool bar.

## 2.1.6 Master Data Change Logging

Most attributes of all master data objects can be edited as long as in status *Created* or *Active*. Changes of master data objects are logged using change documents. Within the data cockpit, all changes that happen to an object are visualized on the tab *Change Documents*.

When searching for master data objects, by default the *Current State* of the object is displayed. Via additional selection *Local Date/Time Old State*, a master data object can also be displayed for a key date. Enter the date and time and then the master data object is displayed in the state it had in the past. On the tab *Change Documents* the change documents which are not respected for the display of the key date are marked with *Temporarily Revoked*. When displayed for a key date, the master data objects cannot be changed (even if the cockpit is in edit mode). The feature *Display for Key Date* is also used when navigating from transactional data to master data objects. For example, when navigating from a serialized trade item (SGTIN) to the trade item (GTIN), the trade item is displayed with the key date when the serialized trade item has been created in the system.

#### i Note

At the time of creation of an object in the system, the master data object state that is currently valid is used to create the transactional object

The following specifics/limitations apply to master data change logging:

#### Business Partners

- **Historic GLNs**: Whenever a GLN assignment to the business partner is changed, a change document is written. To enable performant navigation for historic transactional data, historic GLN assignments additionally are stored in a separate database table.
- **Tab Assigned Plants**: Business partner to plant location assignments are managed at the location. Therefore the corresponding change documents are visible at the location only.
- o **Tab Assigned Systems**: Business partner to system assignments are managed in the system. Therefore the corresponding change documents are visible in the system only. Furthermore system assignments can only be displayed for the current state of the business partner. When you select via a key date, no system assignments can be shown for the old state of the business partner. If you want to verify whether a system has been assigned to a particular business partner in the past, then please evaluate the change documents of the system.

#### Locations

Historic GLNs: Whenever a GLN assignment to the location is changed, a change document is written.
 To enable performant navigation for historic transactional data, historic GLN assignments are stored in addition in a separate database table.

#### Trade Items

The following attributes cannot be changed anymore as soon as the trade item is in the status Active:
 *Trade Item Range Definition, Serial Number Management Type, Business Partner (Customer) to Provide Serial Number, Serialization Profile.* However, there is a professional user transaction /STTP/
 REPL\_RANGE\_DEF, where these attributes can be changed.

#### 

Please use this transaction with extreme care. Read the report documentation and disclaimers before using this transaction. Before doing any changes, the transaction executes a check and evaluates the risk whether the changes can create duplicate serial numbers. However, this check is just an indication and cannot cover all use cases. Therefore, the check cannot guarantee that no

duplicate serial numbers occur when exchanging the range definition. It is the responsibility of the user to ensure that no duplicate serial numbers can occur.

o **Tab Systems**: The trade item to system assignment belongs to the system, and technically is managed in the system. Therefore the corresponding change documents are visible in the system only. Furthermore trade item to system assignments can only be displayed for the current state of the trade item. When you select via a key date, then no trade item to system assignments can be shown for the old state of the trade item. If you want to verify whether a trade item has been assigned to a particular system in the past, then please evaluate the change documents of the system.

## 2.2 Serial Number Management

#### Use

Serial numbers ensure unique identification of objects like Serialized Containers (SSCCs) or Serialized Trade Items (SGTINs) within the supply chain.

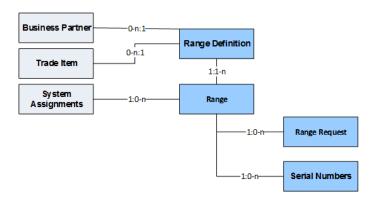
Serial number management handles and organizes definition, creation and distribution of number ranges and number lists and the required master data. This ensures that no duplicate serial numbers are used within the supply chain. Serial numbers ensure unique identification of objects like SSCCs or SGTINs within the supply chain.

Serial number consumers can be provided with number ranges or with number lists. In case a consumer gets a Range, then SAP Advanced Track and Trace for Pharmaceuticals assumes that the consumer ensures that the uniqueness and randomization requirements are considered. In case a consumer gets a serial number list, then Serial Number Management ensures that the uniqueness and randomization requirements are considered.

#### i Note

Serial number requirements may depend on country specific legislation especially in case of China or Brazil. Please refer to Country-Specific Features [page 100].

SAP Advanced Track and Trace for Pharmaceuticals Serial Number Management is based on the following entities:



#### **Features**

- The serialization profile defines how the serial number is composed.
- The range automation profile assigned to the serialization profile handles automated creation, activation and closing of serial number entities like range definition and ranges, both for internally managed and externally managed range definitions.
- Range Definitions define the space within which unique serial numbers can be generated.
- Ranges divide the range definitions into smaller segments that are to be used by different consumers (systems) like a packaging line or a CMO.
- Range Requests are ranges requested by consumers (systems) like a packaging line or a CMO.
- In case of list managed ranges every serial number is instantiated and can be tracked individually (including serial number status management).
- Unique randomization of serial numbers based on the specifications in the serialization profile like type, length, exclusion characters and so on.

#### More Information

Serialization Profile [page 34]

Serial Number Status Management and Serial Number Usage Interface [page 56]

#### 2.2.1 Serialization Profile

The serialization profile is the blue print of the range definition and defines how serial numbers are composed. You can maintain the serialization profile in Customizing at SPRO SAP Implementation Guide Advanced Track and Trace Repository Customizing Serialization Settings Maintain Serialization Profiles .

Besides the serialization profile and its country assignment (or business partner to country assignment for external serial number management type), the range automation profile including ranges to be blocked can also be created here. For more information, see the documentation of the Customizing activity.

The profile contains the following attributes:

- **Profile key**: This is the external identifier of the serialization profile.
- **Serial Number Length**: Defines the length of the serial number; SAP Advanced Track and Trace for Pharmaceuticals supports serial number lengths between 1 and 40 digits.

#### i Note

Most legislations foresee a serial number length of maximum 20 digits.

- **Serial Number Type**: Defines the allowed character set for the generation of serial numbers. Following types are supported
  - Numeric: Allows numbers from 0-9
  - Alphanumeric (capital letters): Allows numbers from 0-9 and the 26 capital characters from the Latin alphabet (A-Z). Further characters (for example, special Characters, punctuation marks, umlaut, and so on) are not supported.
  - Alphanumeric (case sensitive): Allows numbers from 0-9 and the 52 characters from the Latin alphabet (a-z and A-Z). Further characters (for example, special Characters, punctuation marks, umlaut, and so on) are not supported.
  - Alphanumeric (case sensitive) with exclusion list: Allows numbers from 0-9 and the 52 characters from the Latin alphabet (a-z and A-Z). Further characters (for example, special Characters, punctuation marks, umlaut, and so on) are not supported. Furthermore single characters can be removed which means that they will not be used for serial number generation. These single characters are defined in the *Excluded Characters* field of the serialization profile.
- Excluded Characters: This field is only relevant for Serial number type Alphanumeric (case sensitive) with exclusion characters. Please enter numbers 0-9 and characters a-z and A-Z which you want to exclude. Enter the characters without any separators like comma or semicolons.
- **Serial Number Randomization Mode**: Defines how the randomization of serial numbers is done. Following randomization modes are supported:
  - o Non-randomized
  - o Randomized 1:100
  - o Randomized 1:1000

- o Randomized 1:10000
- o Combined Sequential number. + 3 Digit Randomized
- o Combined Sequential number. + 4 Digit Randomized
- Manual Randomization
- External Randomization

#### i Note

In case of external or manual randomization, the external service or function which creates the serial number needs to ensure compliance with the definition (length, type, and exclusion characters). SAP Advanced Track and Trace for Pharmaceuticals system will not check on import whether Serial number length or Serial number type (including exclusion characters) meets the definition. So in case of external or manual randomization, the fields Serial Number Length and Serial Number Type within SAP Advanced Track and Trace for Pharmaceuticals serialization profile are just for information purposes.

For more information about Randomization, see Serial Number Generation and Randomization in the topic Serial Numbers [page 48].

- **Uniqueness Scope**: The serial number uniqueness scope defines how unique a serial number is. The following uniqueness scopes are supported
  - By Trade item: Denotes that the serial numbers are unique within a trade item (GTIN). So two trade items can have the same serial number and they are only unique in combination with the GTIN.

#### i Note

If you would like to use the serialization profile to create range definitions with origin *External*, then SAP strongly recommends that you choose this uniqueness scope, as an automated serial number request to the MAH will be only be possible with this scope .

- By Product Category: Denotes that the serial numbers are unique within a group of trade items
  (GTINs). All trade items with the same serialization profile and the same product category will share
  the same range definition and therefore serial numbers will be unique across all those trade items.
- By country portfolio: Denotes that the serial numbers are unique within all trade items sold within a
  particular country. Two trade items sold within the same country cannot have the same serial number
  but, two trade items sold in two different countries can have the same serial number.
- Globally: Denotes that serial numbers are unique across the globe. So two trade items cannot have the same serial number and are globally unique.
- Reuse Horizon: Defines the number of years after which the serial numbers contained in a range definition version can be reused after closing of the same. Furthermore the reuse horizon implicitly defines the number of range definition versions that will be created (number of versions = reuse horizon +1). In case the reuse horizon is set to 0 then there will be only one range definition version and the numbers never expire and therefore can never be reused again.
- Range Automation Profile: With the assignment of a range automation profile to a serialization profile, the activation of serial number range definition and creation, activation/auto-closing of serial number ranges can be automated. The range automation profile carries all necessary information for automation and is copied to the range definition during creation. The range automation profile is created and maintained in the same transaction as the serialization profile, via the node Range Automation Settings in the dialog structure. Depending on the serial number management type, different attributes of the range automation profile are taken into consideration when creating the range definition and ranges. This is as follows:

- For internally managed serial numbers (*Serial Number Management Type* = *<blank>* or *X*) and randomization mode other than 8-randomized manually all attributes are taken into consideration.
- For internally managed serial numbers (Serial Number Management Type = <blank> or X) and randomization mode = 8-randomized manually only Default Alert Fill Level and Default Threshold are considered. All other attributes and the Ranges to be blocked are neglected.

#### i Note

Randomization mode 8-randomized manually is typically used for Chinese Serial Number management.

- For externally managed serial numbers (Serial Number Management Type = E) only the attributes Default Alert Fill Level, Default Threshold and Default Lotsize are considered and all other attributes and the Ranges to be blocked are neglected.
- **Country Assignment**: Trade items with internally managed serial numbers (*Serial Number Management Type* = *<black>* or *X*) determine the serialization profile via the country assignment. Please maintain all countries for which this serialization profile shall be used, together with the priority.
- Ext. Serno: BuPa-Ctry Assignment: Trade items with externally managed serial numbers (Serial Number Management Type = E) determine the serialization profile via the business partner-country assignment. Please maintain all countries-business partner combinations for which this serialization profile will be used together with the priority.

## 2.2.1.1 Range Automation Profile and Automated Range Handling

Automated range handling is needed to handle the automated cutover from one range to another. With this feature it is possible to do the following:

- Automatically create initial serial number range definitions and ranges, both for internally managed serial numbers and also for externally managed serial numbers
- Close expired ranges
- Create the next range to be used in a mass processing.

A closed range is a prerequisite for archiving of serial numbers, which is very important to keep the serial number database table as lean as possible.

The range automation profile is the starting point for this process. It carries all necessary information for automated range handling.

The range automation profile consists of the range automation profile settings and the definition of ranges to be blocked. The range automation profile is assigned to a serialization profile. The range automation settings of the range automation profile are copied to the range definition at its creation.

The range automation settings are used in the following cases:

- At the initial creation of the range definition: When a range definition is created and the serialization profile has a range automation profile assigned, then the range automation is executed along the following sub-cases:
  - **Standard Case Internal**: For internally managed serial numbers (*Serial Number Management Type* = <*blank*> or *X*) where the randomization mode **is not** *8-randomized manually*, the range definition is created and activated, and all range automation settings are copied to the range definition.

Furthermore, all ranges to be blocked are created and set to status *Closed*. Finally, an initial range is created and activated based on the *Number of Digits for Auto Range* and the range parameters alert fill level, threshold and lot size are copied to the range. The range expiry date is calculated, and if required, the serial number generation is triggered. As a result, the range is ready to be used for serial number requests.

- Special case for Manual Randomization (for example, serial number management for Chinese trade items): For internally managed serial numbers (Serial Number Management Type = <blank> or X) and where the randomization mode is 8-randomized manually also range definition is created and activated but only Default Alert Fill Level and Default Threshold are copied to the range definition. Besides this, no ranges are auto-created because the ranges are created when uploading the serial numbers via a report. For more information see China [page 109].
- **Standard Case External**: For externally managed serial numbers (*Serial Number Management Type* = *E*) the range definition is created with range definition origin *1-External* and the origin system is determined from *Business Partner to Provide Serial Numbers* defined for the trade item

#### i Note

This process requires that the *Business Partner to Provide Serial Numbers* is maintained at the trade item level and further, the business partner must have a *notification system* assigned.

Further, the range definition is activated and here only the attributes *Default Alert Fill Level*, *Default Threshold* and *Default Lotsize* are copied to the range definition. Besides this, only the initial range is created and activated (which is a prerequisite for requesting serial numbers). Finally, a serial number request is created in the system, which has been copied from the business partner to the range definition origin. This requires all relevant parameters to be maintained properly in the system on the tab *Communication Settings*: communication type, serial number request type ,external system name and logical system or logical port. Of course, these settings must be aligned with your serial number provider. Furthermore, the automated serial number request only works if the uniqueness scope of the range definition is *O-by Product*.

- By the report /STTP/SNR\_RANGE\_MASS: This report "closes" expired ranges in two steps and therefore has the following options:
  - Determine expired ranges, set flag number request blocked and auto create new: This report option determines expired ranges (range expiry date is reached or the alert fill level is reached) and sets the flag Number Request Blocked and auto-creates a new range based on range automation settings stored in the range definition. As a result the range with flag Number Request blocked cannot be used for serial number requests anymore, but still can be used for commissioning. The new range now is used for upcoming serial number requests.
  - Close expired ranges: This option only selects active ranges with flag Serial Number Request Blocked and additionally the expiry date, as well as the defined offset in months, must be passed. For the selected ranges the range status will be set to closed and after closing neither serial number requests nor commissionings will be possible for this range. By setting the range status to closed, all serial numbers of this range can be archived which will keep the serial number database table as lean as possible.

For more information, see the report documentation.

#### Range Automation Settings Within a Range Automation Profile

• **Number of Digits for Auto Range**: The field defines how many digits can be used as a prefix for the auto range creation. Please carefully consider before using small numbers like 1 or 2 as the number of ranges will be very limited. If you, for example, define 1 and assign this range automation profile to a numeric

serialization profile then you will only get 10 ranges in total. SAP recommends to define a higher number, for example, 3.

- Range Expiry in Months: This parameter defines how many months after the activation of a range, should the range be retired from active usage.
- **Default Alert Fill Level**: This is the alert level that is used as a default when auto-creating a new range.
- **Default Threshold**: This is the threshold that will be used as a default when auto-creating a new range.
- **Default Lot size**: This is the lot size that will be used as a default when auto-creating a new range.
- Ranges to be Blocked: This defines the prefixes for which ranges shall be blocked. If you, for example, define 0, then one range with prefix 0 will be created and it will be set to status *Closed* so that it can be never used.

#### 

Please ensure that you create range automation profiles that are compatible with the serialization profile to which the range automation profile is assigned to later on. There are certain issues that might lead to error messages during automated range creation, or even to a situation where the processing is stopped. See the following hints:

- Do not define the parameter *Number of Digits for Auto Range Creation* that is too large for the serialization profile. For example, you define *Number of Digits for Auto Range Creation* with 3. If you then assign the range automation profile to a serialization profile that has only 6 digits, and in addition a randomization scope of 1:10000 then the auto range will not contain any usable number, and therefore it cannot be created. The automated range creation then ends in an error that cannot be resolved, and the processing is stopped completely.
- Ranges to be blocked: Do not define prefixes for ranges to be blocked that will result in ranges that
  contain each other: for example, the prefix 1111 is contained in prefix 111. If you maintain this then the
  system first creates and blocks a range with prefix 111, and then the creation of range with prefix 1111
  will fail. However in this case the system will not stop processing because of this error, but will proceed
  with the next ranges to be blocked.

# 2.2.2 Range Definition

#### Use

The Range Definition spans up the potentially available number space that can be used for serial number management.

Besides the ID and the Version, the Range Definition contains the attributes from the Serialization Profile described above, a status, certain statistical attributes, and the expiry date. When you create a serial number Range Definition, the system copies all relevant parameters of the Serialization Profile into the Range Definition. Hence, the Serialization Profile is relevant only until the range definition is created.

The Range Definition allows multiple versions in order to allow reuse of the contained serial numbers after a defined period after its deactivation. This is possible by specifying the Reuse Horizon attribute within the serialization profile. For more information, see Reuse Serial Numbers [page 42].

## Integration

## Trade Item and Range Definition

Trade Item related Range Definitions are typically created or assigned during the Trade Item maintenance. The serialization profile can be determined automatically using *Determine Profile*. The determination is done differently for the different serial number management types, as follows:

- For serial number management type *<blank>* (not defined/not serial number managed) and *X* (internal serial number management) the serialization profile is determined for the maintained profile-relevant country from the serialization profile. If the serialization profile contains the uniqueness scope *By Product Category* then the product category must also be provided.
- For serial number management type *E* (external serial number management) the serialization profile is determined via the combination of business partner and country from the serialization profile. With this, you can define an individual serialization profile for every business partner / country combination if you are acting as a CMO for an MAH.
- If more than one serialization profile is found, the system chooses the profile with the higher priority of the country assignment. Alternatively, you can select the value in the field. The field then displays all the serialization profiles relevant for the profile-relevant country (serial number management types *<black>* and *X*) or for profile-relevant country and business partner (serial number management type *E*). Note that you cannot assign serialization profiles that are not maintained for a particular country (or business partner to country assignment for *External Serial Number Management Type*).

Once the serialization profile is assigned (and if required the product category), you can execute the action *Assign / Create Range Definition* which determines the most suitable range definition for the trade item based on the uniqueness scope of the serialization profile.

- Uniqueness Scope by Product (Trade item): Serial numbers are unique for one trade item (GTIN). So two trade items can have the same serial number and they are only unique in combination with the GTIN. When using the action Assign/Create Range Definition then per trade item a new range definition is created.
- Uniqueness Scope by Product Category: All trade items with the same serialization profile and the same product category will share the same range definition and therefore serial numbers will be unique across all those trade items. When using the action Assign / Create Range Definition then it is determined whether there is already a range definition existing whose Range Definition Group equals the Product Category. If the Range Definition exists, it is assigned. If no such Range Definition exists then it is created and the Product Category of the trade item is copied to the field Range Definition Group of the Range Definition. The value help on the field range definition lists all range definitions which meet the serialization profile and the product category.
- By Country Portfolio: Serial numbers are unique within all trade items sold within a particular country. Two trade items sold within the same country cannot have the same serial number but two trade items sold in two different countries can have the same serial number. When using the action Assign / Create Range Definition then it is determined whether there is already a suitable Range Definition available. If yes this is assigned if not a new one is created.
- **Globally**: Serial numbers are unique across the globe. So two trade items cannot have the same serial number and are globally unique. When using the action *Assign / Create Range Definition* then it is determined if a suitable Range Definition is already available. If available, this is assigned, and if not a new one is created.

After assignment, the Range Definition is stored in the Trade Item master in SAP Advanced Track and Trace for Pharmaceuticals system. Based on this assignment, the Range Definition always recognizes which trade item or items source their serial numbers from it. This approach helps you to assign unique serial numbers per trade item or across trade items.

#### **SSCC Range Definition**

SSCC Range Definitions are created per company prefix to ensure unique numbers for every company prefix. As the company prefix is defined in the Business Partner, the system triggers SSCC management from the Business Partner (on tab Company Prefix and SSCC Serialization) with a similar approach for Trade Item maintenance as described above for. Hence, you can assign a Serialization Profile for every company prefix maintained in Business Partner through the value help and create a Range Definition using the action *Create Range Definition for SSCC*.

#### **Features**

Given below are the important attributes of a Range Definition:

- Range Definition Name: Use this field to provide a short description of a range definition.
- Range Definition Version: A Range Definition Version subdivides the potentially available serial number space into smaller parts, in order to enable reuse after the retention period has passed. You can create multiple versions for a range definition by using the *Create Version* option. Only two versions can be active at the same time during cut-over period from one version to another. If the system has used up a range definition version or it is beyond the expiry date, the version can has to be set to status *Version closed*. You can close the range definition versions only if all underlying ranges are closed as well. When closing a range definition, the system recalculates the expiry date of the range definition and the new expiry date describes the expiry of the retention period of the serial numbers.
- **Serial Number from and to**: This field describes the space covered by a range definition version. Range Definition Status: status of the range definition. The following status values exist:
  - Version Created: After creation, the range definition version is in status *Created*. In this status, you can prepare the range definition version for its later productive use but cannot use it productively.
  - Version Active: Only active versions can be used productively. An active range definition is a prerequisite to activate underlying ranges.
  - Version Closed: You can set a range definition version to status *Closed*. However, the prerequisite is to ensure all underlying ranges to be in status Closed.
- **Alert Status**: This field denotes alerts at a range definition level. The alert status is determined by the report /STTP/SNR\_LEVEL\_CHECK or transaction /STTP/SNR\_ALR\_LEVEL.
- Maximum Serial Numbers: This field denotes the total number of serial numbers that exist within the range definition version. The value indicates the total count of usable serial numbers based on the minimum and maximum serial number and the randomization settings.
- **Expiry Date**: The expiry date of the Range Definition Version has a different meaning dependent on the Range Definition Status
  - Version Active: the expiry date defines the planned end of the active usage of the range definition version. When the version is set to active the expiry date is set to current date + 1 year.
  - Version Closed: the expiry date defines the end of the retention period for the serial numbers contained within the version. After this date is passed a new version can be created covering the same serial numbers.
    - For more information, see Reuse Serial Numbers [page 42].
- Range Definition Group: The Range Definition Group ensures that all Trade Items that share the same Serialization Profile with uniqueness scope "by product category" and the same Product Category will get the same Range Definition assigned.
- Range Definition Origin: This field describes the origin of a range definition. If the origin is defined as internal, it means that the range definition is fully owned and managed by this SAP Advanced Track and

Trace instance. If the origin is defined as external, then the range definition is managed externally by another system and the serial numbers have to be requested from that system. In this case, furthermore, a system has to be provided to which the serial number request will be addressed to. Ensure you maintain the attribute *External System Name* and specify the *Communication Type* and the serial number request type. The solution supports different serial number request types and dependent on the type chosen the communication type can be selected and either RFC settings need to be provided or web service settings need to be provided. For more information, see Serial Number Exchange [page 51].

#### i Note

Important: The range definition origin only can be defined during creation of the range definition and cannot be changed anymore

- **Serialization Attributes**: This section displays the attributes from *Serialization Profile*, which have been copied to the Range Definition.
- Range Automation Settings: This section displays the attributes from the range automation profile that have been copied to the range definition version. All attributes can be changed if range automation settings are changed at a later point in time. For more information, see Range Automation Profile and Automated Range Handling [page 36].
- **Ranges**: This tab displays all ranges that have been created for a particular range definition version. Here you can also create or delete ranges.
- **Trade Item Assignments**: This tab displays the list of all trade items (GTINs) that use this range definition for serial number management.
- **Business Partner (GCP) Assignments**: This tab displays the list of all Business Partners and their GCPs that use the range definition for serial number management.
- Change Documents: Like for master data objects, the attributes of the range definition, which are typically changed by a user on the UI, are logged via change documents and can be displayed on tab *Change Documents*. Attributes, which are changed by the system and not by a user are, however, not logged via change documents. For more information on the general behavior of change documents, see Master Data Change Logging [page 31].

## **Activities**

You can perform the following actions in the results pane:

- Create a new Range Definition
- Create a new Range Definition Version
- Delete a Range Definition Version
- Change the status of Range Definition Version
- Reset the alert status of a Range Definition Version

# 2.2.2.1 Reuse Serial Numbers

## Use

Serial Numbers assigned to a range definition can be reused once the range definition passes the expiry date specified in the Reuse Horizon attribute. This attribute defines after how many years a range definition version (and the contained serial numbers) can be reused again. If you want to restrict reuse of serial numbers, then you can set the reuse horizon value to 0. Thus, the Range Definition will have only one version which never expires (for example, expiry date 31.12.2099).

Furthermore, this attribute defines the number of range definition versions that will be created (number of versions is always equal to the value in reuse horizon field +1).

#### **Process**

- Initial creation of first version
  - When you create a range definition, the first version is created which only covers a part of the overall space (space divided by number of range definition versions). With the creation of a range definition version, the expiry date is set to today + 1 year. While in status *Version created*, the expiry date is given only as information.
- Activation of version
  - At activation of the version, the expiry date is updated again with today + 1 year and this date now defines the expiration date of the active usage of the range definition version.
- Close to expiry of active usage
  - Once an active version passes the expiry date, this version shall not be used actively anymore and the
    version shall be set to status version closed soon. You can use the report Check and Set Alert
    Status to run regularly, in order to determine range definitions that are close to expiry date and set an
    alert status. You can use this alert status to select the range definitions which require action.
- Creation of subsequent versions
  - As soon as a range definition version is nearing its expiry date, a new version needs to be created which
    covers the next portion of the overall space and which will become the next active version. You can
    activate this second version while the first version is still active in order to allow a seamless changeover
    between versions. The expiry date now denotes the expiry of the retention period of the serial
    numbers.

#### i Note

A maximum of two versions can be active in parallel.

- Setting version to closed
  - When setting the status to version closed, the expiry date is recalculated and updated with 'today + reuse horizon'. The expiry date now denotes the expiry of the retention period of the serial numbers.
- Reuse version
  - When the serial numbers have passed the expiry date of the retention period, a new range definition version can be created covering the space of the initial range definition and you can reuse the serial numbers.

# **2.2.3** Range

#### Use

Serial number ranges segment the overall available space into smaller portions within a range definition version. When you create a range definition version, there is always one initial range created, which covers the full space of the range definition version. Depending on the business context, you can further divide the ranges.

#### **Features**

Given below are the most important attributes of the Serial Number Range:

- Range Definition Name and Version: Every range subdivides a range definition version. Therefore, the range carries the context to the range definition and version.
- Serial Number from and to: This attribute describes the space covered by the range.
- Range Status: This attribute describes the status of the number range and also defines what operations are allowed with the respective range. The system automatically chooses the initial range status based on the context of the range definition and the source of the range to be created. Given below are scenarios to use the following status values:
  - Created: Once a range definition is created, a range is automatically created which in most cases has
    the status as created. In this status, you can prepare the range for its later productive use but cannot
    use it productively. Only in this status, you can split or merge ranges using options *Create Range* and *Delete Range*. You can assign systems to the range which is allowed to request serial numbers from
    this range at a later stage in the process.
  - Protected: Ranges in this status are protected against user manipulations because the manipulations
    of these ranges are done by the system only. The status protected is set by the system upon creation
    of the range in the following cases:
    - When ranges of range definitions have an origin value as external and range type value as Range Managed: In this scenario, an initial range in status protected is created. You can now send a range request to the original system. Once you receive the range, it is entered as a new range by splitting up the range that is in protected status. The received range is now in created status and you can now manipulate this range further as described above.
    - o Ranges of range definitions with origin as *internal* and randomization mode 8-manual randomization: In this scenario, the serial numbers can be uploaded from an external source through a report and splitting the ranges is handled by the system. This randomization mode is currently used in case of serial number management for China. While uploading the numbers, the protected range is split and an active range with a prefix is created and the numbers are uploaded to this new active range.
  - Active: Ranges in status active are meant for productive use. Only now serial numbers and ranges can be requested from that range and commissioning can be done for serial numbers belonging to that range. Preparation activities like splitting and merging are not possible anymore. However, you can continue to generate serial numbers. You can also assign systems to the Range. As soon as flag Number Request Blocked is set, no serial number request is possible anymore for a range in status Active and only commissioning will be allowed. This new flag controls the cutover from one range to another to allow closing of a range after a certain period has passed. For more information, see Range Automation Profile and Automated Range Handling [page 36].

#### i Note

When ranges of range definitions have an origin value as external and range type value as *List Managed*, then the ranges are created with status *active* covering the complete space. As their origin is external, you cannot subdivide these ranges. However, you can send serial number requests to the origin system. The serial numbers that are received in response to this request are inserted into the active range.

- Closed: You can set the status of a range as Closed if you do not want to use the range anymore.
   Apparently, no more serial number range or list requests are accepted from this Range and commissioning of distributed serial numbers is not possible anymore. You can close a Range only if all the underlying Range Requests are closed or if all the underlying serial numbers are either commissioned or declared as lost.
  - Force Closing: To close ranges with active sub entries, you can use the option Force Closing. Use
    this option only for Ranges that are in Active or Protected status. This option sets all open requests
    to Closed and all individual serial numbers to Reported lost which are not yet in status
    commissioned or reported lost. By closing range requests, the system automatically considers all
    unused numbers as lost and updates the Range statistics accordingly.

#### 

Please take care while using this option as you can revoke it only partially by activating the range again. Especially, the serial numbers that are declared as lost cannot be activated anymore.

#### i Note

In case of ranges with range definition origin external the report /STTP/SNR\_RANGE\_RECONC Advanced Track & Trace: Range Reconciliation Report needs to be run regularly. Once ranges are closed this report ensures that the serial number usage statistics of the range are sent to the original system who provided the range or list request. The report uses the interface Send / Receive serial number usage information. For more information see Serial Number Status Management and Serial Number Usage Interface [page 56]

- Range Expiry Date: The range expiry date is calculated on the activation of a range, if the parameter Range Expiry in Months is maintained in the range definition version. The range expiry date indicates when this range will expire and will be retired. There is no hard logic implemented behind this expiry date, but this date is used by report /STTP/SNR\_RANGE\_MASS Mass handling of ranges (auto close and create) to select ranges where either the flag Number Request Blocked shall be set, or where the status shall be changed to Closed. This date can be changed at any time on the UI for an active range. For more information see Range Automation Profile and Automated Range Handling [page 36].
- Range Type: This field denotes if the range manages range requests, serial numbers, or both. The Range Type also defines which kind of serial number request can be issued to the range. If the range is of type range managed, you can issue both range request and list request. If the range is of type list managed, you can issue only serial number list requests, as the range cannot return a serial number range. If the range is of type range and list managed, you can issue both range and list requests to the range. The Range Type is set automatically at creation in the following way
  - Ranges of Range Definitions with Origin as *Internal*:
    - The default range type for Numeric and Non-randomized Range Definitions is Range Managed. You can change the Range Type to Range & List managed.

- The default range type for Alphanumeric and Non-randomized Range Definitions is *Range and List Managed*. You cannot change this range type.
- The default range type for all Range Definitions dealing with randomized serial numbers (Randomization Modes 1-9) is List Managed. You cannot change this range type.
- Ranges of Range Definitions with Origin as *External*:
  - The range type for Range Definitions that are set to Numeric and Non-randomized is Range Managed.
  - The range type for all other Range Definitions is always List Managed.
  - The range type of Range Definitions with this Origin is always determined by the system and you cannot change it.
- **Origin indicator**: This displays the origin indicator of range definition. For more information, see Range Definition [page 38].
- **Number Request Blocked**: If this flag is set to true, then no serial number request is possible for an active range. Only commissionings will be accepted. This flag handles the phase out of a range as soon as the expiry date is reached. The flag is set by the report /STTP/SNR\_RANGE\_MASS *Mass handling of ranges* (auto close and create). For more information see Range Automation Profile and Automated Range Handling [page 36].
- **Statistics**: The following attributes are described in this section:
  - o Max Numbers: This field describes the maximum number of serial numbers contained in the range.
  - Sent Numbers: This field describes the aggregated number of serial numbers requested by and sent to consumers (requesting systems.)
  - Commissioned Numbers: This field describes the aggregated number of serial numbers received as commissioning.
  - Numbers Lost: aggregated number of serial numbers reported back as lost.
  - Fill level in %: This field describes by what percentage an available range of numbers has been utilized so far. The calculation of this percentage is as follows:
     Fill level % = sent numbers/max numbers \* 100%
  - Alert Fill Level in %: This attribute defines at which fill level the alert status Alert Fill Level Reached of
    the range is set. Once the fill level reaches the alert fill level, then the alert status is set to Alert fill level
    reached. If a default alert fill level is defined for the range definition version, it is copied to the range at
    creation.
  - Alert Status: This attribute handles alerts at the range level. The alert status is determined either by the report /STTP/SNR\_LEVEL\_CHECK (transaction /STTP/SNR\_ALR\_LEVEL) or based on the Alert Fill Level.
- Serial Number Generation and Request Parameter: The following attributes are described in this section:
  - Serial Number Threshold: It specifies the threshold for numbers that are always available for list requests. If a default threshold is defined for the range definition version, it is copied to the range at creation. If the system detects that the current remaining available numbers, that are ready for a requesting system, is below the threshold value, the system triggers generation of new numbers. The quantity to be generated is defined by the Lot Size.
    - You can generate serial number in three ways:

      On user request through the UI
    - When the threshold has been reached, the generation is triggered automatically
    - Using the report /STTP/SNR GENERATE for generation of Serial Numbers
  - Lotsize: This is the quantity used for both serial number generation and serial number request.

For more information, see Serial Number Generation and Randomization in the topic Serial Numbers [page 48]. If a default lot size is defined for the range definition version, it is copied to the range at creation.

- Range Requests: This tab displays all individual range requests that have been made for a particular Serial Number Range. This tab is only relevant in case the range is range managed or range and list managed and range requests have been made. You can navigate to the Range Request by double clicking on a Range Request. For more information, see Range Request [page 47].
- Serial Number Usage: This tab displays aggregated information about serial number list requests. The form area on top shows aggregated serial number information across all requests such as generated numbers, total numbers sent as list request, commissioned numbers from list managed numbers, numbers declared as lost from list managed numbers. The table below shows one line per system and GTIN (or GCP) and it contains aggregated information across all list requests made for this combination. By Double clicking on one line you navigate to Serial Numbers where all serial numbers are displayed valid for the line. This tab is only relevant in case the range is list managed or range and list managed and list requests have been made. For additional information, see Serial Numbers [page 48]
- System Assignments: This tab displays which systems can request serial numbers or ranges from this Range by explicitly assigning systems to this Range. If one or more systems are assigned to a Range, only the assigned systems can get serial numbers or ranges from this Range. Ranges without system assignment can be used by all systems which are authorized to request serial numbers or ranges for the particular trade item or for SSCCs.
- Change Documents: Like for master data objects, the attributes of the serial number range, which are typically changed by a user on the UI, are logged via change documents and can be displayed on the tab *Change Documents*. Attributes, which are changed by the system and not by a user are, however, not logged via change documents. For more information on the general behavior of change documents, see Master Data Change Logging [page 31].

#### i Note

System authorization is managed in the System entity screen by assigning the attribute Allowed Trade Items or by selecting the options Allow Serial Number Request for All Trade Items and Allow SSCC Range Request. For more details, see System [page 27].

## **Activities**

You can perform the following actions in the results pane:

- Navigate to Range Definition
- Create a new Range
- Delete a Range
- . Change the status of range
- **Generate serial numbers**: Triggers online generation of serial numbers. Only relevant for range types list managed or range & list managed.
- Request Range: Request a range from the external system that owns the serial numbers. Upon receiving the range, it is entered as a new range in status *created*. Now the new range can be used just like an own range. It can be split. Once activated, own systems can request ranges from this range and use them for example, for manufacturing. The action is only relevant in case the range definition origin is external and range type is *range managed*.

- Request Serial Numbers: Request a serial number list from the external system that owns the serial numbers. Upon receive of the list the serial numbers are imported as individual serial numbers in status created. Now own systems can request these serial numbers and use them for example, for manufacturing. The action is only relevant in case of range definition origin external and range type list managed.
- Reset Alert: Reset the alert status of a range.

#### **Specifics for Ranges With Origin** *External*

- Ranges and Serial numbers, which are imported through a serial number request, carry a GCP or GTIN
  designation. They can only be used for the assigned GCP or GTIN, also when the range definition addresses
  multiple GCPs or GTINs.
- Range Reconciliation
  - The report /STTP/SNR\_RNG\_RECONC Range Reconciliation triggers the reconciliation of external ranges that were received from an external system, and sends the serial number usage information to the origin system.
  - If a range is set to status Closed, the reconciliation with the origin SAP Advanced Track and Trace for Pharmaceuticals system is not triggered automatically, because then the status change could not be reverted if executed accidentally. So, the range reconciliation is done only via this report. If you do not want to manually execute this report, then you can schedule it to run regularly. For more information, see the report documentation.

# 2.2.4 Range Request

#### Use

Whenever a consumer (technically, the system owned by the consumer) sends a request for a Serial Number Range, it is reflected in the Serial Number Management as a Range Request. The Range Request documents every request from the consumer and it comprises of the following attributes:

- Range Definition Name and Version
- Serial Number from and to: The Serial Number Range that has been sent to the requesting system.
- Range Request Status: This attribute describes the status of the Range Request. There are two status values:
  - Active / Assigned: After creation of a Range Request, the status is Active / Assigned. This means that the system that requested this range can now actively use it for commissioning.
  - Closed: When a Range Request shall not be used for commissioning anymore, then you can change the status to Closed. When this status is set, the commissioning will not be possible anymore for serial numbers belonging to the Range of serial numbers of the Range Request.
- System Name: This attribute displays the name of the system that requested the range.
- **GTIN or Company Prefix**: A range is always requested either for a GCP or a GTIN. GTIN is provided when the range is requested for a Serialized Trade Item and the GCP is provided when the range is requested for a Serialized Container.
- Statistics: This section displays the following statistical information of the serial numbers that are part of this range request Sent numbers, Commissioned numbers, Numbers lost, Serial Number commissioned and scrapped, and Fill Level.
- **Requested on**: Date and time at which the serial number request has been made Updated on: Date and time at which the last update was made to the range request (for example, last commissioning).

#### **Activities**

You can perform the following actions in the results pane:

• Create a new Range Request

#### i Note

This option is used to create a range request in exceptional scenarios on behalf of another system when the consumer system is unable to implement the service to request serial numbers. When executing the action, you have to specify the quantity of serial numbers, the requesting system, and the GTIN or the GCP.

- Change the status of range
- View related Range Definition
- View related Range

# 2.2.5 Serial Number

#### Use

Ranges of type List managed and Range and list managed can handle serial numbers. Every serial number created is a unique instance and can be followed individually throughout its life cycle. The serial number status denotes the current phase of the serial number in its life cycle.

## **Features**

Given below are the most important attributes of a Serial Number:

- Range Definition Name and Version
- Serial Number GTIN: Trade item for which the serial number has been requested.
- GCP: Global Company Prefix for which the serial number has been requested.
- **System**: This denotes the system that requested the serial number. A serial number in status created has no system assigned. Only after the serial number has been requested by and sent to an own system (status assigned / sent) the system is added to the serial number.
- **Serial Number Status**: The serial number supports following status values:
  - 0 Created
  - 1 Assigned/Send
  - o 2 Commissioned
  - o 3 Reported Lost
- Generated on: Date and time when the serial number was generated
- Sent on: Date and time when the serial number was sent to a consumer via a serial number list request.
- Updated on: Date and time when the last update was made to the serial number

#### **Activities**

You can perform the following actions in the results pane:

• Create a Serial Number List Request

#### i Note

This option is used in exceptional scenarios when the consumer system is unable to implement the service required to generate serial numbers. When executing the action you have to specify the quantity of serial numbers, the requesting system and the GTIN or the GCP. Furthermore, you have to specify a file share location where the CSV file containing the serial numbers shall be stored. After the download you can distribute the CSV file to the consumer e.g. by Email or other means.

- Change the status of a serial number: Individual serial numbers can be declared as lost. Select one or more lines in the result list and execute action change status *Report as lost*.
- View related serial number
- View related serial number

# 2.2.5.1 Creation of Serial Numbers

#### Use

The following are the steps involved in creation of serial numbers:

#### **Process**

• Once the serial number is generated, it is in the *created* status. The generation time reflects the date and time of the number generation. GTIN, GCP, and System are not populated after generation of the number as the serial number is not dedicated for a GTIN or GCP yet.

## i Note

**Exception**: In case of external range definitions (range definition origin = *external*) serial numbers are requested from an external system for a particular GTIN or GCP, and imported as serial numbers in this particular context with values in the GTIN or GCP field.

- After the system requests the serial number, the status of the number is assigned/send. Now the request
  time stamp displays with date and time of the request. Furthermore, the system, GTIN or GCP are also
  assigned, indicating that the serial number has been requested from a system and is meant for the GTIN or
  GCP.
- During commissioning, the system determines if the serial number was requested by the same business
  partner when compared to the one commissioning the serial number. Only if this check succeeds, the
  SGTIN can be commissioned using the serial number. In this case, the status of the serial number is
  updated to commissioned and the update time stamp reflects the date and time of the commissioning.
  The status commissioned is one of two final status values.

- The second final status value is *reported lost* which means that the serial number was lost during processing and will not be commissioned anymore. You can set this status in three ways:
  - As a serial number consumer, you can implement a service which is similar to the serial number request. In this service, you can declare individual serial numbers as lost which sets the status of previously requested numbers to *lost*.
  - The serial number with the status reported lost can be set explicitly in the cockpit for particular and individual serial numbers which are in status **assigned/send**.
  - The serial number with the status reported lost can be set through the option force closing at the range level. When executing this option, all numbers that are in the status created or assigned/send and which belong to the range are set to the status reported lost, in order to allow closure of the range.

#### 

Please take care while using this option as you can revoke it only partially by activating the range again. Note that the serial numbers declared as lost cannot be activated anymore.

# 2.2.5.2 Serial Number Generation and Randomization

#### Use

SAP Advanced Track and Trace for Pharmaceuticals can generate or randomize unique serial numbers based on two algorithms with different flavors. The generation considers the definitions specified in the serialization profile like the character set, length, exclusion characters, and so on. In case of alphanumeric serial numbers, the randomizer only supports generation and randomization of numbers 0-9 and characters a-z and A-Z.

#### **Process**

## **Serial Number Generation**

Serial numbers are always pre-generated to allow fast responding serial number requests. The two most important parameters to trigger number generation are threshold and lotsize.

- The threshold defines the quantity of serial numbers that is always available for requests. When the threshold is reached by a request, the system triggers the serial number generation automatically.
- The lotsize defines the quantity of serial numbers that is generated in one generation run.

#### i Note

As of SAP Advanced Track and Trace for Pharmaceuticals 2.0, Feature Package 03, the automatic generation of serial numbers triggered based on the threshold applies the lotsize as many times are required to reach the threshold within one generation run. The same applies to the initial generation as part of the auto-range automation. This means that in cases where the threshold is substantially higher than the lotsize, the duration of the serial number generation takes longer. In case you have connected an external number generator that has limitations regarding the maximum number that can be generated in one call, you should consider implementing the appropriate logic within the respective

BAdl. The report-based serial number generation continues to trigger the generation of exactly one lotsize if conditions for generation are met.

#### **Randomization Mode**

The following randomization modes are available:

- Non-randomized: no randomization; only sequential number management
  - Numeric ranges with this mode support only ranges. You can even request a serial number list from such a range, but internally this is always handled as a range request and hence individual serial numbers are not visible.
  - Alphanumeric ranges with this mode support both ranges and serial numbers. In this case, serial numbers are not randomized but generated sequentially and added to the serial number list.
- Randomized 1:100: From a given range, numbers are randomly chosen in a way that the algorithm picks numbers from the complete range and in total, only 1:100 of the potentially possible numbers of the range are used. For example, if the range carries 10000 numbers, you can pick only 100 numbers from this range.
- Randomized 1:1000: From a given range, numbers are randomly chosen in a way that the algorithm picks numbers from the complete range and in total, only 1:1000 of the potentially possible numbers of the range are used. For example, if the range carries 10000 numbers, only 10 numbers can be picked from this range.
- Randomized 1:10000: From a given range, numbers are randomly chosen in a way that the algorithm picks numbers from the complete range and in total, only 1:10000 of the potentially possible numbers of the range are used. For example, if the range carries 10000 numbers, only 1 number can be picked from this range.
- Combined Sequential number. + 3 Digit Randomized: In this mode, the first part of the serial number is a sequential number and the last three digits are determined randomly. In comparison to the 1:x randomization given above, the whole range is not taken into consideration for randomization.
- Combined Sequential number. + 4 Digit Randomized: In this mode, the first part of the serial number is a sequential number and the last three digits are determined randomly. In comparison to the 1:x randomization given above, the whole range is not taken into consideration for randomization.
- Manual Randomization: Randomization of serial numbers is done externally and the serial numbers are uploaded through a report. This mode is specifically used for China regulatory reporting.
- External Randomization: You can use the BAdl /STTP/ES\_SNR\_EXT\_RAND Advanced Track & Trace: External Randomization to enable call of external randomizer for complex randomization tasks that are not supported by the SAP Advanced track and Trace for Pharmaceuticals randomizer. For more details regarding this BAdl, see the Configuration guide at http://help.sap.com/attp.

# 2.2.6 Serial Number Exchange

SAP Advanced Track and Trace for Pharmaceuticals supports exchange of serial number lists and serial number ranges. It can play both the role of the serial number provider if the range definition origin is *internal*, and it can play the role of the serial number requestor if the range definition origin is *external*.

If you are the provider of the serial numbers with your SAP Advanced Track and Trace for Pharmaceuticals system, then the requestor may be for example, an internal packaging line (line or site server of packaging line), an external Contract Manufacturer (CMO) or maybe also a local SAP Advanced Track and Trace for Pharmaceuticals system if you have a distributed landscape setup.

If you are the requestor of the serial numbers with your SAP Advanced Track and Trace for Pharmaceuticals system, then either you are acting as a CMO and the provider may be a Market Authorization Holder (MAH), or

you are requesting the serial numbers from a central SAP Advanced Track and Trace for Pharmaceuticals instance if you have a distributed landscape.

The provider of serial numbers needs to define one or more systems for every supply chain partner who will request serial numbers. The system is used to identify the requestor in the provider system. This system must be assigned to the business partner that represents the supply chain partner. Also own packaging lines must request serial numbers with a system that is assigned to a business partner which has a role "own organization". Without this assignment a later commissioning of objects using these serial numbers is not possible. At commissioning it is checked whether the system that requested the serial numbers belongs to the same business partner that sent the commissioning event.

For every system representing a requestor the provider can maintain two important parameters: *maximum serial numbers per request* and *maximum outstanding numbers*. With *maximum serial numbers per request* the provider can limit the number of serial numbers that this requestor system may request in one call. With *maximum outstanding numbers* the provider can limit the total numbers outstanding (difference between numbers requested and reported back as commissioned or reported as lost). The outstanding numbers are calculated within a BAdl. The calculation can be adapted or deactivated if wished. The maximum outstanding numbers can be defined for the system representing the requestor on tab details (default for SSCC request and Trade Items) and on tab allowed trade items per trade item.

The requestor of serial numbers also needs to define a system which will be used for the serial number request and assign this system to the range definition with origin *external* as the origin system. In this system, the communication settings must be maintained properly in order to connect to the serial number provider and also the desired protocol and interfaces must be specified there (further details below).

All serial number entities used and furthermore the systems, the trade items and business partners (GCP range definition) involved into serial number exchange must be in status *active*, for a successful serial number exchange both on provider side as well as on requestor side.

The solution supports the following serial number request types with specific interfaces:

- ATTP 1.0 Synchronous
- ATTP 2.0 Synchronous
- ATTP 2.0 Asynchronous

The requestor decides which of the available types to use. If the requesting system is an SAP Advanced Track and Trace for Pharmaceuticals system, then the serial number request type must be selected in the system that is used for the serial number request.

The serial number requestor needs to set up serial number management in a compatible way with the provider. The requestor needs to have certain knowledge about the capabilities of the provider.

If a serial number range on the provider side is *list managed* than a requestor can only request a serial number list.

If a serial number range on the provider side is *range managed* then a requestor typically requests a range, but a list request is also possible (if the provider system is a SAP Advanced Track and Trace for Pharmaceuticals system).

If you are acting as a serial number requestor (for example, you are the contract manufacturer for a market authorization holder) and you set up a range definition with origin *External*, defined the parameters *Threshold* and *Lotsize* for the range definition, and your range definition is only used by exactly one GTIN/GCP, then a serial number list request or a range request is automatically triggered if the remaining serial numbers fall below the defined threshold. Alternatively, you can execute the transaction /STTP/SNR\_REQUEST - *Request of serial numbers* (From the *SAP Menu*, go to Advanced Track and Trace Repository Data Management

Advanced Serial Number Mgmt. . For more information, see the report documentation. All errors that occur during processing are logged in the AIF interface SN\_REQ\_ALT (Serial number request threshold alert) assigned to namespace /STTPS. For more information on the maintained default recipients and alert categories, see the chapter AIF Error Handling in the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

If you are dealing with range definitions with randomization scope 8-Manual Randomization (typically used for Chinese trade items) then an automated serial number request is not possible because the process is mostly manual. So, for a range definition, which manages serial numbers for a Chinese trade item for example, the user needs to request new serial numbers on a web portal, download them, and finally upload them to SAP Advanced Track and Trace for Pharmaceuticals. The only step which can be automated is that after every serial number request, it is checked whether the threshold of available serial numbers is reached. If it is reached, an alert is triggered in the AIF interface SN\_REQ\_ALT (Serial number request threshold alert) assigned to namespace /STTPS. Based on this alert, a user can be notified and so at least SAP Advanced Track and Trace for Pharmaceuticals will tell the user to initiate the manual procedure described above to request and upload new serial numbers. For more information on the maintained default recipients and alert categories, see the chapter AIF Error Handling in the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

If you need to use SOAP communication using different formats and WSDLs you can use communication adapter for serial number exchange. The adapter may use the same WSDL but add or adjust certain data or use a completely different WSDL and map the data accordingly. Adapter can be defined as an attribute of the system (in communication settings, only if communication type is Web Service). If you use adapter standard ATTP processing logic will be omitted. You need to implement adapter processing logic based on BAdl if you need to use it.

# 2.2.6.1 ATTP 1.0 - Synchronous

Here a distinction between serial number list request and serial number range request is done. So the requestor decides whether to request a serial number list or a serial number range and uses the respective interface.

On the provider side, both Web Services as well as Remote Function Modules (RFC) are supported.

If the requesting system is an SAP Advanced Track and Trace for Pharmaceuticals system then only web services are supported. In this case at the requestor side, the communication settings of the system used as origin system must be maintained as follows:

- Communication type: web service call
- External system name: The name by which your system is known in the providing system
- Serial number request type: ATTP 1.0 Synchronous
- Logical port: Enter the logical port used for serial number request to connect to the system of the serial number provider

# 2.2.6.1.1 Serial Number List Request

Here the requestor requests a serial number list and provides amongst others, the following parameters:

- System by which the requestor is identified in the provider system
- Desired quantity of serial numbers
- Either the GTIN if the serial numbers are meant for SGTINs, or the Global Company Prefix (GCP) in case the serial numbers are meant for SSCCs.

The provider executes the request and synchronously sends back the list of serial numbers.

On provider side, on a high level, the following steps are executed:

- Check whether Trade item of GTIN or Business Partner of GCP is active
- Check whether requesting system exists, if it is in status *active* and if it is authorized to request serial numbers for this GTIN or for SSCCs
- Determine range definition for GTIN or GCP and check that it is active
- Determine all active ranges for range definition and system. If no range found, determine all active ranges for range definition without system assignment (active range without system assignment valid for all authorized systems)
- Determine *Maximum Serial Numbers Per Request* for requesting system and check that the requested quantity is smaller or equal. If not the request quantity will be reduced accordingly.
- Determine *Maximum Outstanding Numbers* for requesting system, calculate currently outstanding numbers and ensure that Maximum Outstanding numbers is greater than current outstanding numbers. If not the request quantity will be reduced accordingly.
- Per Range, the following is done:
  - Determine whether the list request can be fully provided from this range. If yes, then provide back the list from this range and exit processing.
  - In case of remaining list request quantity, go to the next ranges and try to get the remaining numbers there. Go on till full request quantity is reached.
  - $\circ\quad$  In case none of the ranges can provide numbers, return with an error message.

# 2.2.6.1.2 Serial Number Range Request

Here the requestor requests a serial number range and provides amongst others the following parameters:

- The system by which the requestor is identified in the provider system
- The desired quantity of serial numbers
- Either the GTIN, if the serial numbers are meant for SGTINs, or the Global Company Prefix (GCP), if the serial numbers are meant for SSCCs.

The provider executes the request and synchronously sends back the range of serial numbers.

On the provider side, on a high level, the following steps are executed:

- Check whether Trade item of GTIN or Business Partner of GCP is active
- Check whether requesting system exists, is in status *active* and is authorized to request serial numbers for this GTIN or for SSCCs
- Determine range definition for GTIN or GCP and check that it is active
- Determine all active ranges for range definition and system. If no range found, determine all active ranges for range definition without system assignment (active range without system assignment valid for all authorized systems)
- Determine *Maximum Serial Numbers Per Request* for requesting system, and check that requested quantity is smaller or equal. If not the request quantity will be reduced accordingly.

• Determine *Maximum Outstanding Numbers* for requesting system, calculate currently outstanding numbers and ensure that *Maximum Outstanding Numbers* is greater than current outstanding numbers. If not the request quantity will be reduced accordingly.

#### → Tip

The logic is encapsulated within a BAdl default implementation. The BAdl can be deactivated or the logic can be changed if wished.

- Per Range, the following is done:
  - Determine whether the request can be provided from this range (fully or partially). If full or partial
    quantity can be provided, then create the range request from this range and return range to the
    consumer.
  - o If nothing can be provided, go to the next range.
  - o In case none of the ranges can provide numbers, then return with an error message.

# **2.2.6.2 ATTP 2.0 – Synchronous**

This is an additional synchronous serial number interface with the following capabilities:

- One interface capable of handling list and range requests:
  - Requestor can optionally specify whether list or range should be returned.
  - If not specified, then the provider side automatically determines whether to return a serial number list or range (dependent on the capability of the underlying range)
- In addition to the pure serial numbers or range, the requestor also can request readily encoded data either as GS1 element string or EPC URI format.
- If serial numbers for Trade items are requested, the requestor can also request for product types other than GTIN, for example, Chinese EDMC code or any other national code type known in the provider system.
- If serial numbers are requested for SSCCs, the requestor can request serial numbers or a range for a particular SSCC extension digit (first digit of SSCC in GS1 Element String, first digit of serial number)
  - Prerequisite: The provider must manually create and activate ranges with the extension digits as a prefix for the particular range definition.
- Available as RFC and Web Service both on requestor and provider side.

The processing logic is similar to the one described above in chapter ATTP 1.0 – Synchronous [page 53], only that there is no distinction between list and range request. For more information, see the configuration guide.

# **2.2.6.3** ATTP **2.0** – Asynchronous

This is the additional asynchronous serial number interface with the same capabilities as the synchronous interface described above in chapter ATTP 2.0 – Synchronous [page 55].

In addition, the following specifics for asynchronous communication apply:

• Callback address of asynchronous response:

Both for the asynchronous RFC as well as for the asynchronous web service, the callback address is not provided within the request message, but maintained at the system on the provider side either as a logical port or as an RFC connection.

#### No protocol change:

The asynchronous response always must use the same communication type as the request. A protocol change is not allowed, and will result in an error. So if a request is done via RFC then the response also has to be done via RFC. So on provider side the communication settings must be maintained appropriately for the requestor system.

• Check that callback is sent back to the same caller:

The asynchronous response will always be done to the same caller and never to a different party's system. When a requestor creates an asynchronous serial number request, then the IP address of the caller is compared with the IP address of the logical port or the RFC connection maintained in the system of the requestor and the response is only sent if the IP address matches. Otherwise the request will result in an error

Asynchronous RFC:

All non-standard callback RFCs that will be used as a response to an asynchronous Serial Number Request must be explicitly whitelisted. The standard SAP ATTP callback RFC is automatically whitelisted. For more information, see the configuration guide.

# 2.2.7 Asynchronous Serial Number Request Response via SAP Information Collaboration Hub

As an implementation of the Communication Adapter for SAP Information Collaboration Hub for Life Sciences, SAP Note 2652536 is provided to cover EPCIS message exchange as well as the process of asynchronous Serial Number Request Response.

# 2.2.8 Serial Number Status Management and Usage Interface

Advanced Serial Number Management is keeping track of the status of the contained serial numbers both in case of range managed ranges and in case of list managed ranges. The interface Send / Receive Serial Number Usage Information enables the requestor of the serial numbers to report lost numbers back to the serial number provider so that the provider also will see correct statistics.

#### Range managed Ranges

In case of range managed ranges the range request carries a summary how many numbers have been requested, how many have been commissioned and how many numbers have been declared as lost.

- The numbers sent are determined when the range request is created.
- The numbers commissioned are increased in case a commissioning event is processed with one or more items with numbers from that range.
- The numbers lost can be provided through the interface Send / Receive Serial Number Usage Information.

Once the sum of commissioned and lost numbers of a range request equals the sent numbers then the range request is fully executed and the status automatically is changed to closed.

However, there are cases where the sum of commissioned and lost numbers never will equal the sent numbers because e.g. the consumer is not able to implement the interface *Send / Receive Serial Number Usage Information* mentioned above. In such cases, the status of the range request can be changed to "closed" and with this the open quantity of serial numbers is declared as lost. After the status change no further commissionings can be done for the range request.

# **Serial number list managed Ranges**

In case of list managed ranges every serial number carries its own status like *Created, Assigned/Sent, Commissioned* and *Reported Lost*. The status is updated whenever the individual serial number is touched during processing.

- When it is generated then the status is set to Created
- When it has been requested within a list request by a system the status is changed to Assigned/Sent
- When the object is commissioned for that serial number the status is changed to Commissioned
- The status can be set to *Reported Lost* either manually for individual serial numbers within the results pane of serial numbers or the consumer can provide the numbers declared as lost through the interface *Send / Receive Serial Number Usage Information*.

# **Send or Receive Serial Number Usage Information**

The interface Send / Receive Serial Number Usage Information enables a status update for requested numbers or ranges especially to declare the numbers as lost. The interface can be used for range and list managed ranges. SAP Advanced Track and Trace is capable of sending and receiving data through the interface.

In case the system acts as the serial number requestor then the interface is triggered through the reconciliation report /STTP/SNR\_RANGE\_RECONC SAP ATTP: Range Reconciliation Report which considers and reconciles all closed ranges to the original system.

In case the system acts as a serial number provider then the consumer needs to implement the interface and the system can receive and process the usage information.

# 2.2.9 Additional Functionalities for Advanced Serial Number Management

# 2.2.9.1 Check and Set Alert Level for Range Definitions and Ranges

#### Use

This report examines all active range definitions and ranges and determines whether an alert status needs to be set.

Through the selection parameter of the report, you can specify whether the alert status shall be determined for range definitions or ranges and you can define horizons which are considered to advance the alert setting in order to have reaction time.

# **Prerequisites**

Run the following report: SAP Menu SAP Advanced Track and Trace Repository Data Management Advanced Serial Number Management STTP/SNR\_ALR\_LEVEL - Check and Set alert level for Namespace definitions and Ranges.

## **Process**

#### **Set Alert Status for Range Definitions**

- The range definition supports following alert status values: initial (no alert), close to expiry date.
- In order to determine the alert status for range definitions mark the respective checkbox and optionally provide the horizon before expiry in days.
- The report examines whether the expiry date of all active range definition version falls within the current date plus the horizon and if true sets the alert status of the range definition version to close to expiry date.

#### Set Alert Status for Ranges

- The range supports following alert status values: initial (no alert), Alert fill level reached and confirmation overdue.
- In order to determine the alert status mark the respective checkbox and optionally provide the horizon before expiry in days and/or the Days Offset since Last Activity.
- The alert status Alert fill level reached is not determined by this report but always calculated dynamically whenever the fill level is updated in the range (this typically happens with range- or list requests).
- The report deals with the determination of the alert status confirmation overdue which has the following flavors.
  - The report determines whether for active ranges the related range definition version is close to expiry
    date but also still active. Like for the range definition version above here also the horizon before expiry
    in days is considered for the determination and if the range definition falls into the horizon the alert
    status is set to confirmation overdue for the respective range.
  - The report determines whether ranges with long periods of inactivity still have open serial numbers to be confirmed. Here you need to specify the selection parameter Days Offset since Last Activity. Based

- on this parameter all active ranges with the last change date that lie outside this horizon are selected and it is determined whether these ranges still have serial numbers to be confirmed (sent numbers do not equal the sum of commissioned numbers and lost numbers) and if so the alert status is set to confirmation overdue.
- o In case the alert status is already set for a range then it is not overwritten by this report. In order to avoid this you need to process the existing alerts regularly and reset the status in order to allow to redetermine the status based on a new situation.

You can access the report at this path: SAP Menu SAP Advanced Track and Trace Repository Data

Management Advanced Serial Number Management STTP/SNR\_ALR\_LEVEL - Check and Set alert level for Namespace definitions and Ranges.

You can schedule the report in a regular cadence in order to ensure that the alert status is re-determined timely.

After the report has been executed you can select the range definitions and ranges in the data cockpit for a particular alert status. So you will only see those entities with an alert. You can process the range definition or range according to the alert status (for example, close a range definition version close to expiry date) and then manually reset the alert status via the action offered in the results plane.

# 2.2.9.2 Generation of Serial Numbers

#### Use

This report examines all active ranges with range type list managed and range and list managed and determines whether serial number generation has to be triggered for this range.

#### **Process**

#### **Report Selection Parameter**

- Trade item: if you specify one or more trade items then the respective range definitions are determined to which the trade item is assigned and from there all active ranges with correct range types are determined.
- Filter by threshold and distance to threshold in %:
  - If you do not select the checkbox filer by threshold then the threshold is not taken into consideration for the range determination. This as a consequence means that basically all ranges that meet the other selection or filter criteria will be considered for serial number generation.
  - If you select the checkbox filter by threshold then you also need to provide a positive value in field distance to threshold in %. By this it can be controlled that the number generation is started before reaching the threshold value. Remember that as soon as the threshold is reached serial number generation is triggered dynamically and this will result in system load during potentially critical timeframes. So by triggering the generation earlier via this report the generation can be moved into times when system load is low.
- Filter by range type and range: if you select the checkbox filter by range type you also need to specify the range types which shall be considered. Only the following two range types make sense: *list managed* and range & *list managed*.

Based on the selection parameter the report determines all relevant ranges where serial number generation shall be triggered and then generates the given lotsize of serial numbers. If no lotsize is defined at the range then no generation is triggered.

You can access the report at the following path: SAP Menu SAP Advanced Track and Trace Repository

Data Management Advanced Serial Number Management STTP/SNR\_GENERATE - Generation of Serial Numbers

Numbers

Numbers

You can schedule the report in a regular cadence in order to ensure and control that the serial number generation is executed during a time of the day when the system load is low.

# 2.2.9.3 Move Serial Number List Entities to Shadow Table

The serial number list database table may become very large over time. In order to keep this database table lean, SAP recommends to archive serial numbers as early as possible (see Mass Handling of Ranges [page 60] and also Archiving Serial Number Data [page 207]). Archiving is only possible for ranges in status closed. This report /STTP/SNR\_MOVE - Move SNR List Entries to Shadow Table is an additional option to reorganize the database table before closing the corresponding range. This report only works for list managed ranges with the following randomization modes: *O-non-randomized*, *5-combined sequential* + 3 digit randomized, 6-combined sequential + 4 digit randomized. If this prerequisite is fulfilled then the report moves all serial numbers with a final status commissioned or reported lost to the shadow database table. For more information, see the the report documentation.

# 2.2.9.4 Mass Handling of Ranges

The serial number list database table may become very large over time. In order to keep this database table lean SAP recommends to archive serial numbers as early as possible. Archiving is only possible for ranges in status *closed*. Therefore SAP recommends that you create small ranges and use them for a small timeframe, and close them regularly and then archive the serial numbers. Range automation and mass handling helps you to do this. You can define a range automaton profile and assign it to the respective serialization profile. In the range automation profile you can define number of digits used for auto range creation and also an expiry in months for the range. When this is maintained, then at creation of the range definition an initial range is created with the prefix and activated in a way that it can be readily used. This report /STTP/SNR\_RANGE\_MASS - Mass handling of ranges (auto close and create) now automates the ongoing management of ranges. Instead of manually closing ranges and creating and activating new ones, this report uses the range automation parameters to detect ranges to be closed via the expiry date of the fill level, and closes them in two stages. First the expired range is blocked for serial number request and a new range is created and activated using the range automation settings and then in a second step the expired range is set to status closed. For more information, see the report documentation and Serialization Profile [page 34].

# 2.2.10 Serial Number Management Data Change Logging

Some attributes of range definitions and ranges have the characteristics of master data attributes. The other attributes have the characteristics of transactional data. Changes of master data attributes of range definitions

and ranges are logged using change documents. Within the data cockpit, all changes of master data attributes of range definitions and ranges are visualized on the tab *Change Documents*. As not all changes of range definitions and ranges are logged, it is not possible to display old states of ranges definitions and ranges.

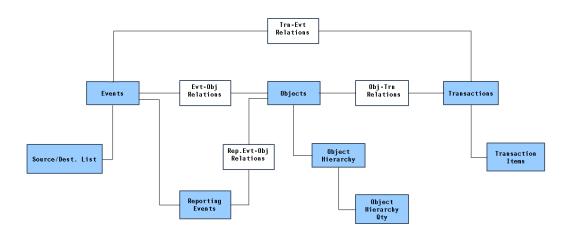
# 2.3 Repository Browser

#### **Definition**

The Repository Browser provides all the transactional object related entities of SAP Advanced Track and Trace for Pharmaceuticals.

#### **Structure**

The data model of SAP Advanced Track and Trace for Pharmaceuticals consists of the following core entities:



- Events
- Objects (of types Lots/Batches, Serialized Trade Items, and Serialized Containers)
- Transactions
- Reporting Events

These entities may have sub entities and they are inter-related with each other by entity relations. The following picture shows the simplified data model:

#### **Objects**

Objects are the heart of the solution and can represent either serialized or as well non-serialized entities.

Objects have the following common attributes:

- They have an identifier which can be encoded or decoded in different representations such as GS1 element string or EPC URI format.
- They have a status, logistic status, pack status, and disposition.
- Serialized items have a business location indicating the currently known location.
- They have relations to events that manipulated the objects.
- They can be part of a hierarchy.
- They can have relations to business transactions such as production orders or deliveries.
- They can have relations to reporting events.

Certain object attributes may be changed based on events received. The solution does not trail the history of such attributes within the object itself. The object only reflects the current state. However, you can reconstruct the attributes that can be changed through the event data. SAP Advanced Track and Trace for Pharmaceuticals is able to store the current object hierarchy. In order to be able to reconstruct historic hierarchies, the object-event relationship carries a parent indicator.

#### More Information

- Lots [page 62]
- Serialized Trade Items [page 65]
- App for SAP Advanced Track and Trace for Pharmaceuticals [page 95]
- Serialized Container [page 66]
- Events [page 67]
- Reporting Events [page 69]
- Business Transaction [page 71]
- Object Tracing and Event Processing [page 78]

## 2.3.1 Lot

#### Use

Lot is also known as a Batch or LGTIN and is a non-serialized quantitative object with a quantity that is typically more than 1. A physical lot may be present at the same time in many different places with partial quantities and therefore cannot be uniquely identified.

A lot is identified by its GTIN and its lot number and you can convert it into different representations like GS1 element string (example –(01)03953720000003(10)BT290504) or EPC URI format (example – urn:epc:class:lgtin:395372.0000000.BT290504).

#### **Features**

In comparison to the other object types the lot has the following specific attributes:

- GTIN
- Lot Number
- Expiry Date: This field denotes the date when a serialized trade item or batch expires.
- **Manufacturing Date**: This field denotes the date when a batch, and therefore all serialized trade items belonging to that batch, has been produced.

#### i Note

Expiry date and Manufacturing date can be changed only as long as the lot is *not released* (disposition = non sellable other). In case a lot is *released* (disposition = active), manufacturing and expiry date cannot be updated anymore. In this case the lot based EPCIS event message will be processed without updating manufacturing and expiry date, and a warning message will be logged in the application log.

- Produced Quantity: This field describes how many units of a batch have been produced so far.
- Lot Disposition Values: As a lot is an object with a quantity more than 0, it typically occurs at many places and might have many different states at the same time. This leads to various generic GS1 disposition values that do not make much business sense. Hence, this field describes the current business condition of the object. You can change the values by using EPCIS events. The following three dispositions are supported for lots:
  - active corresponds to ECC batch status "unrestricted" (meaning: batch is released)
  - In non-sellable other corresponds to ECC batch status "restricted" (meaning batch is not released)
  - Inactive de-commissioned

All other disposition values will be ignored during event processing for LGTINs. Disposition changes to a lot are recorded only if the event message carries no quantity in the quantity list, meaning the whole lot is addressed.

## Lots without serialized items (lot level traced batches)

The Serialization type of trade item is Lot Managed. This means that in SAP Advanced Track and Trace for Pharmaceuticals, only the lot exists and no serialized items refer to the lot. This option has been implemented to support the requirements for the US DSCSA Lot level traceability. For more information, see Country-specific Features [page 100]. Only in case of lots without serialized items, lot quantities can be aggregated into SSCCs and once this is done, the quantities can be tracked or traced through the SSCC. In this case, the aggregated lot quantities are visible in the object hierarchy both for the lot and also for the SSCC.

## • Lots with serialized items (serialized batches)

The Serialization type of batch is Serialized or Serialized and Traced. Besides the lot, serialized trade items exist that refer to the lot. Hence, every serialized trade item carries a reference to its respective lot. Therefore, for a particular lot, the related serialized trade items can be determined and displayed and counted as summary information.

#### **Activities**

You can perform the following actions in the selection screen:

• Post manual events to rectify data within the repository

#### More Information

App for SAP Advanced Track and Trace for Pharmaceuticals [page 95]

# 2.3.1.1 Creation of Lots

#### Use

You can create the LGTIN object explicitly based on an EPCIS event for LGTIN classes or implicitly based on an EPCIS event for SGTIN instances referring to a batch.

#### **Process**

In general, there are 4 possibilities to create an LGTIN object within SAP Advanced Track and Trace for Pharmaceuticals repository system:

- Object Event, Action ADD, Quantity List (with or without quantity), ILMD (Instance Lot Master Data),
   Business Step commissioning
- Object Event, Action ADD, Quantity List (with or without quantity), Extension Attributes for LOT, Business Step commissioning
- Object Event, Action ADD, EPC List, ILMD, Business Step commissioning
- Object Event, Action ADD, EPC List, Extension Attributes for LOT as reference for SGTINs, Business Step commissioning

If the lot data is passed as part of an event with SGTIN objects (EPC list), an AutoCreate LGTIN event with the known batch attributes (all extension attributes matching the lot object attributes) is triggered. The disposition of an auto-created LGTIN will always be active.

#### i Note

Only one Instance Lot Master Data (ILMD) segment can be transferred within one event. The ILMD segment applies to all entries within the quantity list and the EPC list. This solution ignores ILMD for object types SSCC. If both ILMD and extension attributes are provided, the ILMD is considered and the extension attributes are ignored.

Within this repository capture framework, all LGTIN events other than the explicitly supported ones are ignored. In other words, the event is logged and a relation is created, but no updates on the LGTIN are made.

#### Lot Object Locations:

Within the SAP Advanced Track and Trace for Pharmaceuticals repository events which contain a Business Location, may potentially change the location of objects and thus affect the historic locations for LGTIN objects also. Therefore, objects events which may change location reference to related LGTIN objects, in addition to the objects included within the events.

# 2.3.2 Serialized Trade Items

#### Use

A Serialized Trade Item (SGTIN) typically represents a saleable and uniquely identifiable pharmaceutical product.

Serialized Trade Items are identified by GTIN and the serial number. It can be converted into different representations like GS1 element string (for example, (01)07501200000027(21)815022410000000004) or EPC URI format (example, urn:epc:id:sgtin:750120.0000002.8150224100000000004).

SGTINs always have a quantity equal to 1 in its UOM and therefore can only be at one place and in one state at a given time. Therefore, SGTINs can be included within an object hierarchy. SGTINs typically carry a lot reference. In such a case, the lot for an SGTIN can be determined and displayed and the lot data such as expiry date or manufacturing date can be displayed together with the serialized item.

#### **Features**

In comparison to the other object types, the SGTIN has the following specific attributes:

- GTIN
- Serial Number
- Trade Item Identifiers: This section displays, for the selected SGTIN, the values of GTIN, Serial Number, GS1 element string, and the EPC ID URI.
- Trade Item Data: This section displays the Status, Pack Status, Logistic Status, and Disposition of the SGTIN
- Trade Item Business Location: This field displays the currently known location of the serialized trade item.
- Lot Data: This section displays the lot which is referenced by the SGTIN.

## **Activities**

You can execute the following actions from the selection screen:

- Related Events: Navigate to the view Events and select and display all events related to the serialized trade item
- Related Business Transactions: Navigate to the view Business Transactions and select and display all business transactions related to the serialized trade item.

- Menu: Post Manual Event: Enables you to compose and post different kinds of event messages
- Special Functions Request Control :
  - This function is only relevant if you have a distributed SAP Advanced Track and Trace for Pharmaceuticals landscape with a central instance, and one or more local instances. Through this action, you can request control for a serialized trade item which is known in this system but is currently in status 2 – Visible (Read Only). This means that the change control for this object currently is in one of the other systems in your landscape, and no events can be received in your landscape.
  - By executing this action, you can request control for this object from the other systems in your landscape and if the action succeeds, the status will change from 2 Visible (Read Only) to 1- Active.
     As a consequence, the object can receive event messages in this SAP Advanced Track and Trace for Pharmaceuticals instance.
  - It is possible to request control in a central system from a local system and vice versa, and even from one local to another local one via the connected central system.

## More Information

App for SAP Advanced Track and Trace for Pharmaceuticals [page 95]

# 2.3.3 Serialized Container

#### Use

A serialized shipping container code (SSCC) is a uniquely identifiable transport unit like a pallet or a carton. Serialized containers typically carry a hierarchy of lover level SSCCs and hierarchies of SGTINs. The top level SSCC of a packaging hierarchy is the object which is tracked and traced in the supply chain and all events captured with respect to the top level object are inferred to the child objects.

Serialized containers are identified by the GS1 element string which contains the GS1 global company prefix and the serial item reference. You can convert the SSCC into alternative representations such as the EPC URI.

Serialized containers always have a quantity equal to 1 and therefore can only be at one place and in one state at a given time. Therefore serialized containers can be included within an object hierarchy.

#### **Features**

In comparison to the other object types the SSCC has the following specific attributes:

- **Serialized Container Identifiers**: This section displays the GS1 Element String, EPC URI ID, Company Prefix, and Serial Reference (also known as Serial Number).
- **Serialized Container Data**: This section displays the Status, Pack Status, Logistic Status, and Disposition of the SSCC.
- Serialized Container Business Location: This section displays the GLN, Location EPC ID, and the Location Number attributes.

#### **Activities**

You can execute the following actions from the selection screen:

- Related Events: Navigate to the view Events and select and display all events related to the serialized container.
- Related Business Transactions: Navigate to the view Business Transactions and select and display all business transactions related to the serialized container.
- Menu: Post Manual Event: Enables you to compose and post different kinds of event messages.
- Special Functions > Request Control >:
  - This function is only relevant if you have a distributed SAP Advanced Track and Trace for Pharmaceuticals landscape with a central and one or more local instances. Through this action you can request control for a serialized container which is known in this system but is currently in status 2 Visible (Read Only). This means that the change control for this object is currently in one of the other systems in your landscape, and no events can be received in your landscape.
  - By executing this action, you can request control for this object from the other systems in your landscape and if the action succeeds the status will change from 2 Visible (Read Only) to 1- Active. As a consequence, the object can receive event messages in this SAP Advanced Track and Trace for Pharmaceuticals instance.
  - It is possible to request control in a central system from a local system and vice versa, and even from one local to another local one via the connected central system.

## More Information

App for SAP Advanced Track and Trace for Pharmaceuticals [page 95]

## 2.3.4 Events

#### Use

Events are the main entry point into SAP Advanced Track and Trace for Pharmaceuticals transactional data processing. Events trigger creation, update, and deletion of Objects and Transactions and their relations to each other. In other words, you can change the transactional data only through Events and through no other means. Furthermore, the solution only allows you to create an event but not change it. If an event contains wrong objects or has changed the wrong data, you can create another event or even a series of events to rectify the error.

SAP Advanced Track and Trace for Pharmaceuticals object and event model is oriented at the GS1 EPCIS Event data model. The primary data exchange format in inbound and outbound deliveries is EPCIS. SAP Advanced Track and Trace for Pharmaceuticals is capable of receiving PML events as well. They are, however, transformed into an EPCIS-like structure before passed to the event capture framework.

The following EPCIS event types are supported:

- Object Event
  - Create, change and delete (de-commission) objects
- Aggregation Event
  - Aggregate and disaggregate objects
- Transaction Event
  - Add and remove transaction relations to objects
- Transformation Event
  - Transformation Events in SAP Advanced Track and Trace for Pharmaceuticals can be used in two ways:
     One possibility is to use them according to the EPCIS specification for decommissioning an input list and commissioning an output list. They can also be used, by choosing a dedicated specific business step, to assign a new lot number to a set of objects.
  - The default usage for a Transformation Event is to track the decommissioning of a set of existing objects and the following commissioning of a set of new objects. The outputs of the Transformation are created out of the inputs.
  - A special use-case introduced for Transformation Events is the assignment of a new lot to SGTINs that already carry an assignment to another lot. For this, a special business step (sap\_assigning\_new\_lot) has to be used.
  - Please see the configuration guide for further details on how to set up the solution to work with transformation events.

#### i Note

Currently, the event type Quantity Event (EPCIS 1.0 deprecated) is not supported

SAP Advanced Track and Trace for Pharmaceuticals is capable of receiving (capturing) and sending EPCIS events based on the above supported event types.

Events do not have an external identifier. Events are identified by the date and time when they occurred.

#### **Features**

The Event has the following attributes:

- **Event Type**: This field displays the type of event that has been triggered. The supported types are Object Event, Aggregation Event, Transaction Event and Transformation Event).
- **Event Action**: This field displays the action that was triggered by the event type. The event actions are Add, Delete, and Observe. Transformation Events do not possess an action.
- Event Time (UTC) and Time zone Offset to UTC: The time and date of events is always captured and displayed in UTC format.
- Business Step (according to GS1 Core Business Vocabulary): This field specifies the business context of an event
- **Disposition** (according to GS1 Core Business Vocabulary): The disposition of an event specifies the business condition of the objects, subsequent to the event. The disposition is assumed to hold true until another event indicates a change of disposition. Intervening events that do not specify a disposition field have no effect on the presumed disposition of the object
- **Business Location**: The business location specifies the location of the objects, subsequent to the event. The business location is assumed to hold true until another event indicates a change of the business

- location. Intervening events that do not specify a business location have no effect on the presumed location of the object. This value must be provided in SGLN format.
- **Readpoint**: The read point specifies at which location the event happened or was recorded. According to GS1, a Read Point is a discretely recorded location that is meant to identify the most specific place at which an EPCIS event took place. This value must be provided in SGLN format.
- Transformation ID: An optional identifier that can be used for connecting several Transformation Events. If provided, this ID must be in CBV XFORM format. The transformation ID will be saved as a Business Transaction with a dedicated type.

#### **Event Inference and Event – Object relation**

Events carry a reference to all objects that participated at the event. Events are typically captured for the top object of a packaging hierarchy. During event processing, all child objects of the current hierarchy are determined and the event is inferred to all child objects. A native indicator at the event-object relationship, stores the information in the following ways:

- Native Indicator is true: Whether the particular object has directly participated at the event
- Native Indicator is false: Whether the event was inferred to the object

Events are also inter-related to the other entities:

- The Business Transactions tab can be used to display all transactions that participated in an event. For more details, see Business Transaction [page 71].
- The Reporting Events tab can be used to display all reporting events that have been created for a particular event. For more details, see Reporting Events [page 69].

#### **Activities**

You can perform the following actions in the selection screen:

- Display related business transactions
- Display related AIF Message
- Display/download related XML message
- Trigger Rules
  - This opens a pop up to show which rules would be triggered and in which order, given the current rules framework setup (similar to transaction / STTP/SIMU RULES Rules Framework Simulation)
  - The event is used as an input for rules processing, therefore a reporting or another rule will be retriggered given the parameters of this event, the current master data and system settings.
  - This can be used for setting the current time stamps in reporting events or for restarting a reporting, if during the initial posting of the event, the master data was not maintained correctly or completely.

# 2.3.5 Reporting Events

#### Use

The reporting event is used to document Regulatory Reporting and Supply Chain Reporting. The reporting event represents one reporting message and carries all necessary information which is needed for

administration and reviewing regulatory or supply chain messages. One event can be split into multiple reporting events in order to allow splitting of large event messages by batch or any other means which are required for legal reasons. Furthermore, the reporting event allows monitoring and handles approvals like batch release and manual approval. It allows re-triggering of messages in case of errors or acknowledging error messages that cannot be sent in their current state.

The reporting event carries a relation to the event that created it. It also carries a relation to all objects that are part of the reporting event message. In addition, the reporting event carries a reference to the corresponding AIF (Application Interface Framework) message and the XML file which is submitted through AIF. For more details, see Central Message Processing, Notification Monitoring and Error Resolution based on SAP Application Interface Framework (AIF) at <a href="http://help.sap.com">http://help.sap.com</a> Technology Framework SAP Application Interface Framework The reporting event is created from a regulatory reporting rule or a supply chain reporting rule. While configuring BR, you can define if the reporting event has to be sent immediately to the receiver or if the message should be held back till the batch release or user approval. Once the reporting event is created, these parameters are copied from the rule to the reporting event. For more information on Rules customizing, go to SPRO SAP Implementation Guide Advanced Track and Trace Repository Customizing Rule Customizing.

#### **Features**

The Reporting Event has the following attributes:

- **Created on**: Like the Event, the reporting event has no meaningful external identifier and instead the creation date and time is used as an identifier.
- Sent Time: Documents the date and time at which the reporting event was sent to the receiver.
- Rule Type: This field documents the rule type which was determined during rules processing and which actually triggered the creation of the reporting event. For more information, go to SPRO SAP Implementation Guide Advanced Track and Trace Repository Customizing Rule Customizing.
- **Status**: This field shows the status of the reporting event.
- **Country Group**: This field documents the country group which was determined during rules processing and which triggered the reporting event. For more information, go to SPRO SAP Implementation Guide Advanced Track and Trace Repository Customizing Rule Customizing.
- Wait Batch Release: If this option is set the reporting event is not sent to the receiver until the batch is released and furthermore implicitly the one separate reporting event per batch is created. The flag is set at creation of the reporting event and determined from reporting customizing. For more information, go to SPRO SAP Implementation Guide Advanced Track and Trace Repository Customizing Reporting Customizing.
- Lot Number: If the Waiting for Batch Release option is set, the relevant batch is referenced in the reporting event.
- Wait User Approval: If this option is set the reporting event is not sent to the receiver until a user explicitly approves the reporting event in the data cockpit. The flag is set at creation of the reporting event and determined from reporting customizing. For more information, go to SPRO SAP Implementation Guide Advanced Track and Trace Repository Customizing Reporting Customizing.
- **Approved by**: This field displays the user name of the person who has approved the release of a regulatory reporting notification message (only relevant in case the option *Wait User Approval* is set).

- **Approval Time**: This field displays the time when the user approved the release of a regulatory reporting notification message.
- The following attributes are only relevant for asynchronous response messages (for example, in case of communication with the European Hub):
  - Response Status: The response status displays an aggregated status across all asynchronous responses received for a reporting event.
  - Expected Responses: The attribute expected responses displays the overall number of asynchronous response messages that are expected to be received from the EU hub.
  - Open Responses: The attribute open responses shows the number of response messages still open.



You can search for reporting events with open responses by selecting the checkbox *Only Open Responses* in the search pane.

#### **Activities**

You can perform the following activities in the results pane:

- Display related events
- Display related AIF Message
- Display/download related XML message
- Approve a reporting event
- Resend a message
- Acknowledge an error status

#### More Information

Regulatory Reporting and Supply Chain Reporting at Outbound Processing [page 89]

# 2.3.6 Business Transaction

#### Use

Business transaction documents (or business transactions) reflect business documents like production order, inbound or outbound delivery. They are stored as a separate entity within the SAP Advanced Track and Trace for Pharmaceuticals transaction data repository.

Business Transaction documents can be created in two ways. They can be created explicitly via integration from ECC and furthermore they will be created implicitly "on the fly" in case they are referred within an EPCIS document and do not exist yet. For further details, see Creation of Business Transaction [page 74].

If business transaction documents are integrated from SAP ECC, then they also carry item information from SAP ECC. If the item was split in SAP ECC (can happen for outbound delivery) then the parent item is displayed above the split items.

## **Features**

The Business Transaction Document has the following attributes

- **Transaction Code**: This is the external identifier for the business transaction. It is always shown in the encoded EPC URI format and contains the GLN and the document number. The transaction code is only unique together with the business transaction type.
- **Business Transaction Type**: This is the type of business transaction according to GS1 Core Business Vocabulary.
- **Document Status**: This describes the current status of the business transaction document. The following are the status values created externally, initially integrated, closed or finished, deleted in source system, and replicated. For further details, see Transaction Status Handling [page 74].
- **GLN of Business Transaction**: This describes the Global Location number which is specifically used for authorization check.

In case a transaction is integrated from ECC, the following additional ERP attributes are relevant:

- **Document Number and Type**: This gives the number and type of the business transaction. Only when the number is combined with the document type and GLN or Logical System, it can clearly identify a single document.
- **Global Location Number (GLN)**: identifies the GLN (plant level GLN) where the document originates from. The document number and the GLN are used to encode the business transaction code.
- **Logical System**: In case the business transaction document is integrated from an ECC system, the logical system id of that originating ECC system is documented here.
- **Transaction Summary Status**: This describes the cumulative status that the items of the corresponding business transaction document in the ERP system are in.
- Ship from GLN, Sold from GLN, Ship to GLN, and Sold to GLN: These fields give information about the GLN of the location of the shipment.
- Transaction Items: This tab displays the items of the business transaction. Items are only provided in case the business transaction is integrated with ECC. Only those items are integrated from ECC to SAP Advanced Track and Trace for Pharmaceuticals which are relevant for serialization or lot management.
  - Item Number: This attribute denotes the document position or item used in the corresponding ECC business transaction document, for example, Inbound Delivery.
  - Global Trade Identification Number (GTIN)
  - Transaction Item Status: This attribute denotes the business transaction item status from ERP and shows the current status of a particular item in ERP. For further details, see Transaction Status Handling [page 74]
  - Planned Quantity: Reflects the actual planned quantity of the business transaction item in ECC.
  - Confirmed Quantity: Reflects the actual confirmed goods movement quantity of the business transaction item in ECC.
  - Lot number: Batch / lot number that is assigned to the item
  - In case of split items (can happen for outbound deliveries for example in case different batches are
    executed for one item) both the parent item as well as the split items are displayed. The parent only
    carries a planned quantity as long as the total planned quantity is not fully assigned to the split items.

- Action *Compare Serialized Items* launches a popup that compares planned items and their confirmed item quantities with actual quantities in the repository system.
  - The main purpose of this function is to ensure that both ECC goods movement data, as well as serialized repository data are in sync and consistent.
  - This function compares all items and confirmed item quantities of the business transaction document with the actual serialized items that are currently assigned to the business transaction document (see also Transaction-Object relationship below).
    - Confirmed quantitiy: confirmed quantity that reflects goods movements posted in SAP ECC for this particular item
    - Item count: Counted number of serialized trade items that have a current relation to this business transaction document and which can be assigned to this item because both the GTIN and Lot are the same as in the planned item.
  - This popup can deal both with quantity deviations as well as structural differences.
    - Quantity deviation: A quantity deviation exists for a given item, when it has an item count in the repository system that is more or less than the goods movement quantity in ECC. Quantity deviations are visible as Item difference.
    - Structural difference: whenever a serialized trade item has a current relationship to a transactional document and either the GTIN and or the Lot does not match with any of the planned items, then this case is treated as an unplanned item and displayed with a special item id XX... in the popup. So in this case there are serialized trade items assigned to a business transaction document that do not match with any existing item. Therefore this indicates a significant structural deviation.

Transactions have relations to events and objects.

#### Transaction-Event Relationship

- Documents that a transaction participated in a particular event
- As events can only be created and not updated, the transaction-event relationship is available permanently.

#### Transaction-Object Relationship

- Documents transaction and the object that are currently related to each other
- This relationship can be created and removed with the help of Events.

#### **Example**

- A transaction event with action ADD creates a business transaction relationship between the objects in the
  object list of the event and the business transaction. After the event, all objects carry this transaction
  relation.
- A transaction event with action *DELETE* removes the transaction relationship between the business transaction and the objects contained in the event.
- An object event with action observe which includes a business transaction reference confirms that the objects contained in the object list still belongs to a particular transaction. Even if this reference does not exist, it is created implicitly.

#### 2.3.6.1 Creation of Business Transaction

#### Use

Business transactions can be created in two ways:

#### **Process**

- Explicit creation through ECC integration
  - The SAP Advanced Track and Trace for Pharmaceuticals add-on for ERP offers the option to integrate certain business transaction types. In this case these business transactions are integrated from ECC at creation (for example, deliveries) or release (for example, production, process order) of the business transaction. Furthermore the business transaction will be created with items and the processing status of the business transaction is integrated as well and reflected as business transaction item status and transaction summary status. For more details, see Transactional Data Integration [page 179] and Transaction Status Handling [page 74].
- Implicit creation of business transaction through EPCIS event:
  - If there is a business transaction reference within an EPCIS message and the business transaction has not yet reached the repository system, then the business transaction is created as an external business transaction together with the transaction relations.
  - o In this case, the business transaction serves as an abstract linked object which can be used to search for objects or events but have no connection to an existing transaction within ERP.
  - Through this approach any supported business transaction type beyond the currently supported ECC transactions can be created and referenced within SAP Advanced Track and Trace for Pharmaceuticals.
    - The document status will always be created externally and the transaction summary status will always be Created as EPCIS only supports transaction references but does not handle transaction status information.
    - The ERP attributes mentioned above are not displayed completely.
    - The Business Transaction will not have items as EPCIS does not support transaction items.

## 2.3.6.2 Business Transaction Status Handling

#### Use

This topic explains how the different status fields like the document status, transaction summary status, and item status depend on each other. As mentioned above, the business transaction document status is relevant for all kinds of business transactions. In case of an externally created transaction, the document status is set to created externally at creation and never changed again.

The real status handling only takes place in case the business transaction is integrated with ECC. In this case, the document status reflects the overall status of the document. The business transaction summary status is an aggregated view of the item status values and the item status receives updates from ECC.

#### **Process**

#### **Document Status**

- Created externally: Only status used for external business transactions
- Initially Integrated: Initial status value for business transactions integrated from ECC
- Closed or Finished: Transaction summary status is closed
- Deleted in Source System: Set in case business transaction is deleted in ECC
- Replicated: Used in case of distributed repository systems to indicate that business transaction has been replicated; for details see, Distributed Deployment [page 157].

#### **Transaction Summary Status**

- Created: Initial status after creation of business transaction
- In Process: First item is in status *In Process*
- Closed: All items are in status GM posted
- Deleted: Is set in case all items have been removed

#### **Item Status**

- Created: Initial status after creation of item
- In Process: Partial confirmations on item level in ECC
- GM posted: Final confirmation done at item level in ECC

### 2.3.7 Authentication Requests

#### Use

The solution offers the capability to authenticate Serialized Trade Items (SGTINs) and Lots (LGTINs), and documents all successful and failed authentications as an authentication request.

The authentication request behaves a little differently depending on whether it is done internally or externally. The distinction between internal and external authentications is done via the system that must be provided with every request. If the system is assigned to a business partner which has a role *Own Organization*, then the Authentication Request is treated as internal. Otherwise it is treated as external.

Within one authentication request, one or more objects can be authenticated. For every object provided, the solution tries to decode the object code. The object code typically is submitted as GS1 element string and alternatively can be submitted in EPC URI format or any other format that the solution can decode (for example, Chinese EDMC code). Depending on the encoding, different information can be provided. If GS1 Element string is provided, then this string can contain further elements that will be also decoded and checked if provided:

- GTIN: Application identifier (01)
- Serial number: Application identifier (21)
- Lot number: Application identifier (10)
- Lot expiry date: Application identifier (17)
- Lot manufacturing date: Application identifier (11)

If the decoding is successful, the solution checks whether the object exists in the repository. Depending on the provided information, it is checked whether only the SGTIN exists (only 01+21), or whether only the LGTIN

exists (only 01+10), or whether both SGTIN and LGTIN exist and if the LGTIN belongs to SGTIN (01+21+10). If the expiry date (17) or manufacturing date (11) are provided, then, in addition, it is checked whether these dates are correct.

Besides the existence check, the following additional checks are done for an SGTIN:

- Authentication with internal system
  - o Object status must be other than Invalidated
  - Object disposition must be in list of *Allowed Dispositions for Internal Systems* (maintenance in transaction /STTP/AUTHENT DISPO *Allowed Dispositions*) -
- Authentication with external system
  - Object status must be other than Invalidated
  - Logistic status must be Shipped or Sold

#### → Remember

An external authentication cannot be successful if the object still resides in own warehouse.

 Object disposition must be in list of Allowed Dispositions for External Systems (maintenance in transaction /STTP/AUTHENT DISPO - Allowed Dispositions)

Optionally, the Authentication request can capture geo coordinates so that such authentications can be visualized on a map.

An Authentication request can be created via either Web Service, OData or RFC. You can use and leverage these interfaces to build applications that create Authentication requests. In addition to these interfaces, a mobile app "Mobile Authenticator" (see Authenticator [page 97]) and two test UIs are also provided to create and test Authentication requests (/STTP/AUTH\_TEST Authentication Request Test Report and on ECC Side: /STTPEC/WHS\_TOOLBOX - WHS Toolbox Test Client, see Tab Auth Request).

The authentication request check logic can be enhanced /adapted within BAdl /STTP/BADI AUTH REQ CHECK OBJ method CHECK OBJECT.

#### **Features**

Authentication requests can be searched and displayed in the data cockpit. An Authentication request consists of the Authentication Request Header and the Authentication Request Items.

#### **Authentication Request Header**

- Authentication time: Date and time when the authentication request has been created.
- **System**: System that was used for authentication. To do an authentication the system must be in status *active*. Systems assigned to a business partner with role *own organization* are treated as internal system. All others as external system.
- User Name: User that created the authentication request.
- **Result of Request**: At authentication request header level you will find a summary result for all authentication items. The result options are the following:
  - o 1 Ok: All items successfully authenticated
  - o 2 Partial ok / not ok: Some items successfully authenticated, some items failed authentication
  - 3 Not ok: All items failed authentication
- **Geo Location of Authentication Request**: Optionally the geolocation can be provided with an authentication request. If provided, the authentication request also can be displayed on a map. The map is displayed in a web browser. For information on configuring the map provider, see the configuration guide at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>

#### Authentication Request Items: Tab Objects

- Authentication Request Item: Item ID of authentication request
- **Object code**: Object code provided for the authentication request item. The solution can authenticate different formats like for example, GS1 element string, EPC URI and Chinese EDMC format.
- SGTIN: Check result for SGTIN
  - o If SGTIN provided (GTIN + Serial number): Ok or not ok
  - No SGTIN provided: N/A
- LGTIN: Check result for LGTIN
  - o If lot number provided: Ok or not ok
  - o No lot number provided: N/A
- Expiry Date: Check result for expiry date
  - o If expiry date provided: Ok or not ok
  - No expiry date provided: N/A
- Manufacturing Date: Check result for manufacturing date
  - o If manufacturing date provided: Ok or not ok
  - No manufacturing date provided: N/A
- Result: Check result for item
  - Summary of all relevant check results for SGTIN. LGTIN, expiry and manufacturing date
  - Result of additional SGTIN check (see above)
- Action: Display Check Results: Displays detailed check results in a popup for the selected item
- Action: Display Serialized Trade Item: Navigates to the serialized trade item
- Action: Display Lot: Navigates to the Lot

## 2.3.8 Historic hierarchy

With this separate transaction, you can display the hierarchy an object was in at any given point in time.

You can enter the code for an object into the field and then either enter a date and time directly, or chose from a list of events for which the hierarchy should be displayed. If you chose an event, the hierarchy will be shown as it was after the event happened. Please consider that event date / time always is displayed in time zone UTC, whereas the date time entered explicitly refers to user time zone.

The hierarchy will be shown in a tree. The tree nodes can be expanded or collapsed.

Currently the functionality is not enabled for lots.

You can access the historic hierarchy by navigating to: SAP User Menu Advanced Track and Trace Repository Data Management Repository Data Management Historic Hierarchies Alternatively, you can use transaction / STTP/HISTHIER.

The historic hierarchy can be displayed also from the cockpit for a selected serialized trade item or serialized container. For this, select a serialized trade item or serialized container and a related event (details screen), or select an event and a related object (details screen) and use *Historic Hierarchy* on the corresponding details screen.

### 2.3.9 Object Tracing and Event Processing

#### Use

SAP Advanced Track and Trace for Pharmaceuticals can receive and process EPCIS and PML event messages. One event message can contain one or more events.

An Event contained in an Event Message documents and traces an atomic business activity that happened to the objects contained in the event. An event therefore contains four main parts:

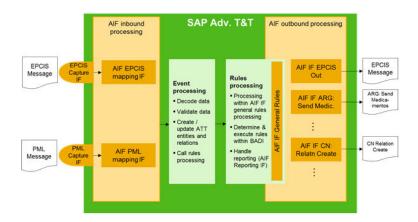
- When: represented by the time stamp of the event
- Where: represented by the read point and business location of the event
- What: represented by the combination of event type and action
- Why: represented by the business step and the disposition, which can be further accompanied by referenced business transactions

#### **Features**

EPCIS describes the following different event types that are to be used to trace events:

- Object Event (Action = ADD, DELETE, OBSERVE)
  - This event type helps to publish the existence or to end the lifecycle of a serialized object. In addition, you can use it to trace any observation to a serialized object. Transaction references can be attached but are not mandatory. The event generally applies to a list of EPCs or LGTINs. Extensions are possible at event header level. The extensions may also reference list of EPCs they apply to.
- Aggregation Event (Action = ADD, DELETE, OBSERVE)
  - This event type helps to publish the aggregation or disaggregation (pack / unpack) of serialized objects to or from a parent EPC. Transaction references can be attached but are not mandatory. The event generally applies to the packing or unpacking activity which references a number of EPCs or LGTINs being added to or removed from a hierarchy. Extensions are possible at event header level. The extensions may also reference list of EPCs they apply to.
- Transaction Event (Action = ADD, DELETE, OBSERVE)
  - This event type helps in adding or removing a transaction reference to or from an object. You can use
    this as an alternative to the object event to observe any activity that is executed with a serialized
    object. The event generally applies to a list of EPCs or LGTINs. Transaction reference is mandatory.
- Transformation Event (no Action)
  - This event type helps to transform input objects into output objects. You can use this to destroy a list of input objects while commissioning a list of output objects at the same time. The event generally applies to an input list and an output list of EPCs or LGTINs. An optional Transformation ID can connect several transformations. If a special dedicated business step is used, this event can be used instead to assign a new lot to a list of objects. In this case, those objects need to be represented in the input and output list and the lists have to be identical.

### 2.3.9.1 Overview End to End Event Message Processing



The Inbound and Outbound processing of event messages is handled through SAP Application Interface Framework (AIF).

Within the AIF inbound processing, the AIF EPCIS mapping interface maps EPCIS messages to internal EPCIS-like structures. For every event contained in the message the SAP Advanced Track and Trace for Pharmaceuticals event processing is called. Similarly, in case of receiving a PML message the AIF PML mapping interface transforms the PML message to EPCIS like structures and also calls the event processing.

The event processing decodes the event and objects data, validates the data, creates or updates all the repository entities (objects, event, transactions) and also the relations between entities. This is followed by the triggering of the rules processing as a background task.

Within Rules Processing, all the relevant rules are determined and then are considered based on the rule sequence. The actual rule is processed within the AIF general rules interface by calling a BADI for every rule. In case of supply chain or regulatory reporting the reporting event is created here, the data is mapped to reporting message structures and another AIF outbound interface is called which enables sending and monitoring of outgoing reporting messages.

### 2.3.9.2 Inbound Processing

### 2.3.9.2.1 EPCIS Inbound Processing

#### Use

EPCIS inbound is possible through SOAP Service and OData Service.

#### **Process**

The AIF EPCIS mapping interface performs the following steps

- 1. It receives the EPCIS XML message.
- 2. It determines whether the message has to be processed sequentially in a queue or can be processed in parallel to other messages and assigns the message to the correct queue.
- 3. It sorts the events within the message based on the event time stamp. In case the time stamp is the same, the events are processed in the order within the event message.
- 4. It splits the message into its single events.
- 5. It maps the data from the external EPCIS XML to SAP internal EPCIS-like ABAP structures.
- 6. It calls event processing separately per event (see topic Event Processing [page 83]).
- 7. It controls the commit handling dependent on the message content and configuration or one of the two (either commit by event or by complete message. More details given below).

#### **Further Information**

#### Parallel Processing and Message Serialization

- You can configure if event messages shall be processed in parallel or sequentially in a queue which
  forces processing in the same sequence of the arrival message. When the processing of one message
  fails, in case of serialized processing, this message blocks the queue and all the subsequent messages
  wait until the blocking message is either removed or reprocessed successfully.
- o You can configure message serialization in the Customizing activity under SPRO SAP Implementation Guide SAP Advanced Track and Trace Message Processing Sender Queue and Commit Settings. Here you can define a sender and per sender, you can maintain whether messages from this sender shall be serialized. If nothing is maintained by default two event messages from a sender will be processed in parallel and independent from each other.
- o In addition to the customizing, the event message needs to contain the sender information. Therefore the EPCIS header can be enhanced with the following extension information

```
<EPCISHeader>
<SAPHeaderExtension>
<SAPQueueMessageSender>
SENDER_OR_QUEUE_CONTENT
</SAPQueueMessageSender>
<SAPHeaderExtension>
```

#### </EPCISHeader>

 Serialized messages are visualized in the AIF message monitor as an aggregate below a tree node for the sender which defines the serialization queue. Messages visualized below undefined node are the ones processed in parallel.

#### • Commit Handling

- Similar to the message processing, you can use the same customizing activity to configure if you want
  the messages from this sender to be committed for every message or if every event contained within
  the message to be committed separately.
- In case of commit by message, even successfully processed events within the same message will be rolled back if any subsequent event fails.
- o In case of commit by event, the successfully processed events are persisted permanently within the repository and cannot be received again.
- In both cases, the failure of an event will stop subsequent events within the same message to be processed.

#### Rollback Handling

- If the event is considered failed during inbound processing, all the non-committed changes are rolled back and the event is considered failed and the AIF inbound message is also considered failed.
- No further events from the same message are processed.
- In AIF, the message appears as failed. The failed inbound messages can be queried and displayed in the AIF monitor. You can review the application log messages and identify the errors. If applicable, you can restart the processing and only those parts of the message that have not been committed are restarted.

#### • Extension Concept for EPCIS Inbound Processing

- SAP Advanced Track and Trace for Pharmaceuticals offers powerful extension capabilities to receive and process custom specific attributes at different levels of the EPCIS XML message.
- In order to process enhanced EPCIS messages, it is not necessary to modify or enhance the definition
  of the EPCIS messages based on a custom WSDL file that has to be implemented by all senders of
  EPCIS messages. Instead, the EPCIS inbound processing only interprets the tags in the message it
  identifies. Unidentified tags are ignored during processing.
- The existing SAP EPC Extensions and a new set of SAP Extensions are supported natively For more information, see the configuration guide at http://help.sap.com/attp.

#### Usage of alternative business partner and location identifiers in EPCIS messages

- The solution allows usage of alternative business partner and location identifiers during EPCIS inbound processing.
- Instead of providing GLNs or SGLNs for tags like read point, business location, event source destination locations or owning parties, alternative identifiers also may be used during inbound processing.
- The used alternative identifiers must be defined at the business partner and location.
- In addition, for the particular registration type the prefix that is used within the message to identify the type must be maintained.
- The corresponding business partner or location must have a GLN/SGLN assigned, and in case an
  alternative identifier is used within an EPCIS message the corresponding GLN/SFGLN is determined
  from the business partner / location and used for data creation. So internally the solution works based
  on GLNs and SGLNs but alternative identifiers can be used in EPCIS messages.
- Example
  - o A supply chain partner does not send EPCIS messages with GLNs but uses DEA numbers instead.

- You need to maintain a business partner/location in your system and assign the GLN/SGLN that shall be used for data processing.
- Besides this you define a registration type in customizing (for example **DEA**) and assign the prefix that shall be used for data processing (for example **DEA**).
- Now define the registration by using the created registration type **DEA** and entering the registration number (for example **xx000007**) plus all other mandatory attributes (see below).
- As soon as the registration is valid, it can be used to receive and process EPCIS messages using these alternative identifiers (for example a read point containing the content DEA: XX000007 instead of the SGLN in EPC URI format).
- For more information, see Business Partner [page 17] and Location [page 21].

#### Asynchronous EPCIS Response

If the EPCIS message was sent using asynchronous SOAP service, it's possible to send an asynchronous response back. After inbound EPCIS processing, the system collects log messages and sends it back through SOAP service. The callback system is determined by the sender GLN provided within the EPCIS message header. The business partner assigned to this GLN has a parameter *Notification System*. The response will be sent to this system if responses are allowed by the business partner (you can configure this using the *Send EPCIS Responses* indicator in the business partner settings) and by the corresponding general Customizing parameter.

### 2.3.9.2.2 PML Inbound Processing

#### Use

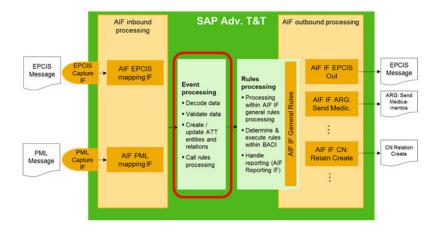
In this solution, the capturing and rules processing works based on EPCIS-like SAP structures and therefore the PML structures need to be transformed into EPCIS-like SAP structures prior to event capturing.

#### **Process**

With this approach, you can call the same event interfaces. You can use the PML Conversion customizing activity to define how a PML inbound message is transformed into an EPCIS event message. For more information, refer to the customizing documentation at \$\rightarrow SPRO \rightarrow SAP Implementation Guide \rightarrow SAP Advanced Track and Trace \rightarrow PML Conversion \rightarrow.

### 2.3.9.3 Event Processing

#### Use



Give below are the high-level steps of Events Processing triggered by the repository system:

#### **Process**

- 1. Decodes the event data.
- 2. Implements BAdI to change the decoded event data.
- 3. Decodes object data Validates activity; implements BAdl for validations
- 4. Checks if the event is the latest for all objects; if not: proceed with late event processing (see details below)
- 5. If configured and relevant: executes auto create or auto unpack and validates activity again.
- 6. Creates or updates the objects including hierarchies
- 7. Creates events; implements BAdI to manipulate specific event data
- 8. Creates event-object relations
- 9. Creates business transactions
- 10. Creates business transaction object relations and business transaction event relations

- 11. Saves the data
- 12. Implements BAdI after processing to change customer-specific data after event processing
- 13. Triggers Rules Processing

For more information regarding the BAdIs available in Event Processing, and regarding the possibility of adapting the event processing through configuration (for example auto create, auto unpack, late event processing), see the configuration guide at http://help.sap.com/attp.

#### **Late Event Processing**

The event processing logic by default checks whether the event is the latest one for the serialized objects in the object list of the event. If the event is not the latest one for at least one of the objects, then the event is treated as late event and the event processing follows a special logic. Processing late events is not trivial because of event inference. Event inference is an important feature from GS1 EPCIS event processing which deals with inferring an event, which has been recorded for a parent object of a hierarchy, down to all child objects contained in the current hierarchy. So if , for example, a shipping event has been recorded for an SSCC then this event is inferred to all child objects of the hierarchy. If now, for example, an late dis-aggregation event is coming in, removing certain objects from the SSCC hierarchy, the late event processing not only would have to deal with posting the aggregation event but also with rectification of inference of later events. In this case the shipping would not be valid for the objects disaggregated with the late dis-aggregation event. This is not at all trivial and therefore most of such complex use cases are not supported as of today. Instead simply the event is recorded without changing the objects for which the particular event is late.

Late events can be blocked from processing in general customizing per event type and event action by setting parameter BLOCK\_LATE\_EVENT\_OBJ, BLOCK\_LATE\_EVENT\_AGG, BLOCK\_LATE\_EVENT\_TRN and optionally the event action. If set to true then in case a late event is detected for any object contained in an event the event processing is stopped right away with an error. If the parameter is not maintained or false then the late event processing is executed and behaves differently for the different event types

- Late commissioning event (object event, action add)
  - Under certain conditions, a late commissioning event can be recorded for objects that already exist in the repository: object exists but no commissioning event recorded (auto creation without commissioning event configured, see section Auto Create below), commissioning event must be the first event for the particular object. Furthermore, late event processing must not be blocked.
  - Following settings need to be done in general Customizing (please find further information in the configuration guide):
    - Ensure that parameter BLOCK LATE EVENT OBJ is NOT TRUE for action ADD
    - Parameter LATE\_OBJ\_EVT\_ADD must be TRUE for the particular GLNs to enable posting of late object events
    - Prerequisites for auto creation without commissioning event
      - AUTOCREATE ITM and AUTOCREATE SCC must be TRUE for particular GLNs
      - $\circ$  AUTOCREATE\_EVT\_EXT and AUTOCREATE\_EVT\_INT must NOT be TRUE for the particular GLNs
- All other late events
  - o In case late event detected and the processing is not blocked, the late event is processed.
  - $\circ\quad$  All objects for which the event is the latest event, the event is processed properly.
  - All objects for which the event is not the latest event the event is recorded, however no object data is changed.
  - Furthermore the event-object relation carries value *L* in the attribute *Native Indicator* to indicate that this event is not the latest for this particular object.

• Besides a warning is recorded in the application log if at least one object is detected for which this event is not the latest event.

#### **Auto Create**

With this feature, the solution provides the option to automatically create an object during event processing if it does not exist yet. During activity validation and event capturing, the system checks if *Auto Create* is active for a particular read point GLN of the event message. If it is active, the objects are auto-created.

You can define and control *Auto Create* separately for SSCC and SGTIN in the *General Customizing* under SAP Advanced Track and Trace for Pharmaceuticals. It can be either activated generally, or for certain GLN of read point of event message. If you wish to activate auto create, you can configure parameter *AUTOCREATE\_ITM* and/or *AUTOCREATE\_SSCC* in *General Customizing*.

Furthermore auto create can be configured to either work with or without a commissioning event via general customizing parameter AUTOCREATE\_EVT\_EXT (for external events) or AUTOCREATE\_EVT\_INT (for inhouse events). If set to *true* then a commissioning event is created. If the parameter is false (default if not maintained at all) then the object will be auto created without a commissioning event. For more information, see the configuration guide at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>.

#### **Auto Unpack**

This feature helps you to reduce the number of detailed aggregation events that need to be transmitted and captured to reflect the internal operations of non-owned warehouses for example, in case of third-party logistics. It allows to receive aggregation events reflecting the final pack hierarchy at the time of shipping from a place outside the own organization even if the last known hierarchy was different. The auto-unpack feature assumes that the hierarchy has changed in case an event is received that refers to an object which is still packed.

You can define and control Auto Unpack separately for SSCC and SGTIN in the *General Customizing* under SAP Advanced Track and Trace. It can be either generally activated or for certain GLN of read point of event message.

Auto Unpack for SGTIN allows following additional configurations:

- No Auto Unpack: The SGTINs are not auto-unpacked.
- Unpack complete parent: When this is activated, the complete parent SGTIN is automatically unpacked as
  soon as one item SGTIN is removed from it. The parent SGTIN ceases to exist after auto unpacking all
  items from it. However, auto unpack will only succeed if all outer packing levels can be auto unpacked as
  well till the outmost packing layer is reached and with this the SGTIN is unpacked from its complete
  hierarchy
  - In case the outer packing levels are also SGTINs then also here the outer parents are completely autounpacked and de-commissioned.
  - o In case the outer packing levels are SSCCs then first it needs to be checked whether auto unpack is configured for SSCCs and which method is configured.
    - If auto unpack is not configured for SSCCs the complete auto unpack for all layers is not possible and the event processing will be stopped with an error.
    - If auto unpack is configured for SSCCs dependent on the method auto-unpack is executed according to the method documented below.

Auto Unpack for SSCCs allows the following additional configurations:

- No Auto Unpack: The SSCCs are not auto-unpacked
- Unpack Object only: When this is activated, individual objects can be unpacked from SSCC hierarchy without affecting the remaining SSCC hierarchy.

- Unpack Complete Parent: When this is activated, the complete immediate parent SSCC is automatically unpacked.
- Also here auto unpack will only succeed if all outer packing levels can be auto unpacked as well till the
  outmost packing layer is reached. As SSCCs can only be child of other SSCCs, auto unpack is simply
  executed iteratively level by level according to one of the methods above, till the outmost packing level is
  reached and the required SSCC is unpacked from its complete hierarchy.

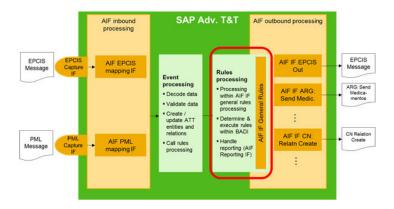
#### i Note

For object type LGTIN or lot, the auto-unpacking option is not applicable as the individual unit of an LGTIN cannot be identified.

Besides the auto unpack, there is an additional option to unpack objects based on a rule you can set up for rule type <code>BR\_UNPACK\_DECOM</code>. If during rules processing this rule is determined, then the hierarchy of all objects contained in the event message is determined, and for all of them all SSCC layers are unpacked and decommissioned but the contained SGTIN hierarchy is kept intact. This rule can be used for example to "flatten" the hierarchy at the time of shipping to an external location. For more information, refer to Rules Processing [page 87].

# 2.3.9.4 Rules Processing

#### Use



The rules processing, on the one hand, is used for supply chain and regulatory reporting but it can also process business rules like "flatten hierarchy at shipping", for example. Certain rule types are pre-delivered by SAP and can be used in the rules definition right away. In addition, custom specific rules can be defined and implemented.

#### **Process**

Rules are configured in customizing. The configuration consists of the following four steps

- 1. Review or define rule types (here you can review all pre-delivered rule types).
- 2. Define location groups.
- 3. Define country groups.
- 4. Define rules.

In addition, here is a simulation report that simulates which rules will be processed in which sequence for a particular event message context.

It is also possible to define and implement custom specific rules. On a high level the following three steps are necessary

- 1. Define custom specific Rule Type.
- 2. Create and implement new BAdI implementation for Rule Type and assign Rule Type as filter value.
- 3. Configure rules in customizing by using the new rule type.

For a detailed understanding of Rules Processing, refer to the Customizing documentation in the system and also to the Configuration Guide at http://help.sap.com/attp.

#### **Business Rule Types**

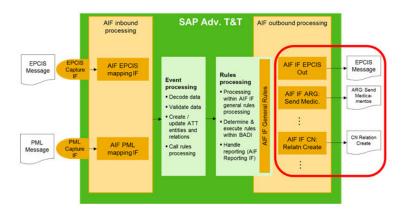
The following business rule types are currently included in the solution:

- BR\_BATCH\_DECOM Bus. Rule: Decommission all Items of a Batch at Batch decommissioning
  - This business rule type reacts on the decommissioning event of a Batch / Lot. If configured as a rule, all serialized trade items (SGTINs) that refer to the Batch / Lot that is decommissioned are detected, and a decommissioning event for all SGTINs is composed and posted.
- BR\_BATCH\_RELEASE Bus. Rule: Send messages on hold after batch is released
  - This business rule type reacts on a batch release event. It checks whether for this particular batch there are reporting events waiting currently for the batch release, and if so, the outbound communication is sent to the receiver. You can configure whether the outbound message for a particular rule type shall only be sent if the batch is released, in transaction /STTP/CUST\_REP\_ATT Define Rule Type Settings for Reporting via checkbox Waiting for Batch Release. So when a batch is not released when creating the reporting event, and the checkbox Waiting for Batch Release is selected, then the reporting event is created, but the message is not sent. When the batch release event is processed and this rule is configured appropriately, then the outbound communication is triggered
- BR\_DISTR\_DM Business Rule: Replication of transactional data
  - This business rule type is only relevant if you have a distributed SAP Advanced Track and Trace for Pharmaceuticals landscape. If you have such a landscape, then you need to set up this rule to automatically distribute the transactional data between the systems.
- BR\_UNPACK\_DECOM Bus. Rule: Unpack complete and decomission of hierarchy obj
  - This rule type determines the hierarchy of all objects contained in the event message, and for all of them all SSCC layers are unpacked and decommissioned, but the contained SGTIN hierarchy is kept intact. This rule can be used for example, to "flatten" the hierarchy at the time of shipping to an external location.
- BR\_BATCH\_DECOM\_HIER Bus. Rule: Deletes completes hierarchies for a decommissioned batch
  - This rule determines all related objects for the decommissioned batch, getting the whole hierarchy to the top level including parent SGTINs and SSCCs. If another GTIN is included in the hierarchy, the system checks whether the lot number for SGTINs and SSCCs is the same as the decommissioned batch. This is necessary in order to support more than one level of SGTINs. In case of inconsistent hierarchies (different lot numbers, branches with other GTINs, and so on), the system stops the processing of the rule. In case of a correct hierarchy, the system creates a new decommissioning event with all the collected items of the hierarchy including SGTINs, SSCCs, Lots with the same lot number.
- BR\_BATCH\_SHIPMENT Bus. Rule: Batch Shipment
  - This rule can be triggered for a shipping event that was created for an LGTIN. The rule determines all
    related objects for batch shipment, getting the whole hierarchy including parent SGTINs and SSCCs. If
    another GTIN is included in the hierarchy, the system checks whether the lot number for SGTINs and

SSCCs is the same as the shipped batch. This is necessary in order to support more than one level of SGTINs. In the case of inconsistent hierarchies (different lot numbers, and so on) the system stops the processing of the rule. In the case of correct hierarchy, the system creates a new shipping event with all the collected items of the hierarchy including SGTINs, SSCCs, Lots with the same lot number and triggers SCP notification.

### 2.3.9.5 Outbound Processing

#### Use



SAP Advanced Track and Trace for Pharmaceuticals is able to compose and send outbound messages in different formats to different kinds of receivers. These receivers typically are either a government server in case of regulatory reporting or another supply chain partner in case of supply chain reporting. The receivers typically are connected via Web Service but in exceptional cases (for example, China) also a file based exchange is supported.

#### **Process**

The outbound processing is triggered within the rules processing. In case of rules which trigger Supply Chain Reporting or Regulatory Reporting, a reporting event is created within the rules processing and the data is mapped to the outbound message structure.

Only now the outbound processing is triggered. Another AIF outbound interface is called to handle the actual sending of the outgoing messages. This approach enables dedicated monitoring of the outgoing reporting messages. Please find further details regarding supported country specific outbound messages in the topic Country-specific Features [page 100].

#### Regulatory Reporting and Supply Chain Reporting Framework

The Regulatory Reporting framework is embedded into the rules processing and outbound processing features of SAP Advanced Track and Trace for Pharmaceuticals. For every supported country, SAP delivers a set of rule types for regulatory or supply chain reporting which handle the creation of the respective reporting events and reporting messages. Based on the rule type, one can configure rules in Rules Customizing. Once such a rule is executed, one or more reporting events are created which document the relation between the triggering event and the objects contained in the reporting event. The reporting event also holds the link to the AIF message and the XML that contains the actual reporting message content. For more information, see Reporting Events [page 69].

The Regulatory Reporting Framework supports following features based on configuration settings for a particular rule type:

- Ability to hold message until user approval: If this setting is configured for a rule type, only the reporting
  event is created during rules processing, but no message is sent to the receiver. The message is only sent
  once the explicit approval is made. User approval can be given in the Reporting Event entity in the Data
  Cockpit.
- Ability to hold message until batch release: If this setting is configured for a rule type, the system checks
  during event processing if the related batch is released. If the batch is not released, the reporting event is
  created, but the message is not sent to the receiver. When a batch is released, the message will be sent if
  the rule for rule type RR BATCH RELEASE is configured.

For more information regarding supported regulatory reporting messages see Country-specific Features [page 100].

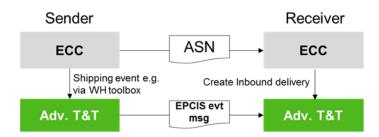
#### **EPCIS Outbound**

Besides the country-specific reporting, SAP Advanced Track and Trace for Pharmaceuticals also supports neutral EPCIS outbound message processing which can be used to inform a subsequent supply chain partner for example, about objects commissioned, aggregated (if appropriate) and shipped (if appropriate).

Sending an EPCIS outbound message is one of two general possibilities you have to provide your subsequent supply chain partners with serialization information.

- Possibility 1: Advanced Shipping Notification + EPCIS message
- Possibility 2: Enriched Advanced Shipping Notification (eASN)

This topic deals with the EPCIS outbound message of possibility 1. You can find more information on possibility 2 in chapter Enriched Advanced Shipping Notification (eASN) [page 191].



#### There are three different options to create an EPCIS outbound message:

- Option 1: EPCIS outbound message triggered by a shipping event, composed within a rule and sent as a Web Service directly to the receiving business partner.
- Option 2: EPCIS outbound message triggered by any object event, composed within a rule and stored to a file
- Option 3: EPCIS outbound message triggered and composed by a report and configurable outbound capabilities (file or web service)

# Option 1: EPCIS outbound message triggered by a shipping event, composed within a rule and sent as a Web Service directly to the receiving business partner.

The rule composes the EPCIS message, determines the receiving business partner and sends the EPCIS message as web service directly to the receiving business partner. This EPCIS outbound only can be triggered by a shipping event. It can be configured by creating rules that use rule type <code>SR\_INFORM\_SUCC</code>: Supply Chain Partner: Inform Successor.

The resulting EPCIS outbound message will contain the following events:

- Commissioning events for all shipped objects: Serialized Trade Items, Serialized Containers, and Lots that are referred within the Serialized Trade Items
- Aggregation events to compose the shipped hierarchy
- Shipping Event declaring the shipment of the top level objects (typically pallet SSCCs)

#### i Note

Important notes and prerequisite:

- Only use this rule type to create rules for business step shipping as only in this context all relevant information is available.
- The receiving supply chain partner must be maintained as business partner and this business partner
  must have the notification format EPCIS assigned and a notification system must be maintained
  capable of receiving the web service.

# Option 2: EPCIS outbound message triggered by any object event, composed within a rule and stored to a file

In this case the notification format is not determined from the receiving business partner but is always EPCIS by default. Therefore this rule can be triggered from any object event with action *ADD* or *OBSERVE* and even works based on an aggregation event with action *ADD* under certain conditions. This rule composes the EPCIS message and stores it in the mapped file share. It can be configured by creating rules that use rule type SR INFORM SUCC FILE: *Supply Chain Partner: Save Successor Notification into File*.

The content of the EPCIS message depends on the triggering event and always contains commissioning events and optionally aggregation events and a shipping event dependent on the context.

- Commissioning events: Commissioning events for all objects determined for the object contained in the triggering event.
  - If the objects of triggering event are aggregated: commissioning for the objects contained in the triggering event plus commissioning for all child objects that belong to the hierarchy.
  - If the objects of triggering event are not aggregated: commissioning event for all objects contained in the triggering event.
- Aggregation events: Only if objects of triggering event are parent of hierarchy
  - If the objects of the triggering event are parent of hierarchy: aggregation events to compose the current hierarchy.
- Shipping event: Only in case the triggering event is a shipping event.

For more information regarding the file share setup, see the configuration guide at http://help.sap.com/attp.

# Option 3: EPCIS outbound message triggered and composed by a report and configurable outbound capabilities (file or web service)

With this powerful report you can compose and send EPCIS outbound notifications. Objects for notifications and events are selected based on various selection criteria. You can also compose and post internal EPCIS receiving and shipping events.

The objects are selected based on different selection criteria. There are five ways to determine objects:

- Lots by GTINs: Select lots for a particular GTIN and manufacturing date within horizon, and determine serialized objects of this lot and exclude all objects that have a disposition to be excluded
- By individual Lot: Determine serialized objects for a particular lot and exclude all objects that have a disposition to be excluded
- By finished business transaction: Determine business transactions that have status closed/finished and last change date within horizon and determine all objects related to this business transaction and exclude all objects that have a disposition to be excluded
- By individual business transaction: Determine all objects related to this business transaction and exclude all objects that have a disposition to be excluded

• By top level Object: Determine all child objects for provided top level objects (SGTIN or SSCC). In case at least one object has a disposition to be excluded the processing is stopped immediately

If the objects to be reported are part of a hierarchy, and some of the objects in the hierarchy have a disposition that has to be excluded from reporting, then the complete hierarchy is not reported, with a corresponding error message.

Within processing option *Compose internal EPCIS* event for objects you can optionally compose and post internal shipping or receiving events for the selected objects. This might be especially helpful if you want to compose EPCIS outbound messages for partial quantities of a lot or transaction, and still want to ensure that every item only is contained once in an EPCIS message.

**Example**: You are producing large multi day batch sizes, and you are shipping out every evening a partial batch quantity to the supply chain partner. This you can achieve by object selection *by individual lot*. You enter the lot there and add disposition in transit to the list of dispositions to be excluded. Furthermore *select compose and post shipping event* and the wished option for the outbound event message. Now you can run this report every evening and it always will select all objects that have not been shipped out yet, and then compose a shipping event and the supply chain outbound message. So after the report is run, all items that are contained in the outbound message now have the disposition in transit and will not be selected for reporting again the next evening.

Within the processing option "compose supply chain outbound event message" you will have to choose one of the options:

- EPCIS to file: The EPCIS outbound message is composed and stored to the same fileshare as for the rule SR\_INFORM\_SUCC\_FILE. For further details please see Rules Processing [page 87].
- Web Service: The EPCIS message is composed and sent via web service
   Prerequisite: Notification system must be provided. For this system communication type web service
   must be defined and logical port must be maintained. In case you need to use custom format and WSDL
   communication adapter must be defined for notification system and corresponding BAdI with custom
   processing logic must be implemented.
- None: No outbound message composed. This option exists because you can also use this report only to trigger an internal event (for example, a shipping event) and then use a normal rule for outbound processing.

The Supply Chain notification can be composed as standard EPCIS message as well as with US-specific (US Lot and US Item) format extensions.

You can also include and exclude certain kinds of events from the final supply chain notification. The following options are available:

- Commissioning events
  - No Commissioning Events all commissioning events are excluded
  - No Commissioning Events for Lots commissioning events for corresponding LGTINs are excluded
  - Include All Commissioning Events all corresponding commissioning events are included
- Decommissioning events
  - No Decommissioning Events all decommissioning events are excluded
  - Include Decommissioning Events corresponding decommissioning events are included
- Aggregation events
  - No Aggregation Events all aggregation events are excluded
  - Virtual Aggregation Events (Current Hierarchy) artificial aggregation events are created in correct sequence to reflect current hierarchy

- o Actual Aggregation Events (Complete History) all corresponding aggregation events are included
- Shipping events
  - o No Shipping Events all shipping events are excluded
  - Last Shipping Event Only only last shipping event is included
  - o All Shipping and Receiving Events all corresponding shipping and receiving events are included

You can split objects to be reported by assigned lot or by top level hierarchy object, and send a separate notification for each list of objects.

You can execute the report in simulation mode, meaning only the selection of objects, the composing of internal EPCIS events and the composing of supply chain notification will be performed, but without posting these to Capturing Framework and Application Interface Framework.

The report can be accessed via the SAP Menu Advanced Track Trace Repository Data Management Repository Data Management Transaction /STTP/CREATE\_EPCIS - Select objects and trigger EPCIS notification.

Alternatively the report can be accessed via transaction /STTP/CREATE\_EPCIS - Select objects and trigger EPCIS notification.

For more information, see the report documentation.

### 2.3.10 Requesting EPCIS messages

Besides the possibility of creating and pushing EPCIS messages to a receiver (see Outbound Processing [page 89]), SAP Advanced Track and Trace for Pharmaceuticals also offers the possibility for authorized systems to request (pull) EPCIS messages either via Remote Function Call (RFC) or via a web service. For more information, see the developer guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

### 2.3.11 Extending the Data Cockpit UI

The data cockpit can be extended in the following areas with custom specific fields and screen elements:

- A custom search can be implemented.
- Custom fields can be displayed in the results pane.
- Custom fields and other customer-specific controls such as custom tables can be displayed in the details area on a specific tab.

For more information, see the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

# 3 Web Applications Along with SAP Advanced Track and Trace for Pharmaceuticals

#### **Definition**

SAP Advanced Track and Trace for Pharmaceuticals provides web apps that you can use in addition to the traditional SAP GUI UIs. The web apps focus more on occasional users whereas the SAP GUI UI is meant for professional users. Therefore, the web apps mainly focus on display of data. Moreover, they do not display all entities, but currently focus on transactional objects (no master data or serial number management).

The web apps can be integrated into an existing SAP Fiori landscape. You can access the applications from the SAP Fiori Launchpad.

The following app can be used on desktop and tablets:

#### Data Cockpit

This app allows you to obtain a view of the following main transactional entities of SAP Advanced Track and Trace for Pharmaceuticals: Serialized Trade Items, Lots, Serialized Containers, Events, Reporting Events, Business Transactions and Authentication Request. Moreover, you can display the historic hierarchy for a particular object.

The following two apps can only be used on smartphones and tablets and require a camera:

#### Authenticator

This application allows you to authenticate a serialized trade item by scanning the barcode with your mobile device. The app submits an authentication request to the connected SAP Advanced Track and Trace for Pharmaceuticals system and displays the result of the authentication. For more information, see Authentication Requests [page 75].

#### Mobile Warehouse

This application allows warehouse managers to scan a barcode of a serialized trade item or a serialized container with their mobile device and to obtain information of the item, for example, decoded barcode, object type, trade item description, status of item, list of events in which the item participated, aggregation information and many more. Besides this you can use this app to post correction events for the scanned item.

#### i Note

Although this app is not delivered as part of the SAP Fiori app catalog, it follows the SAP Fiori design paradigm.

### 3.1 Web Data Cockpit

#### Use

The Data Cockpit is another option to view the repository objects through a Fiori-like app. The web browser displays similar features like the *Repository Browser* in the *SAP Advanced Track and Trace for Pharmaceuticals:*Data Cockpit in SAP GUI for the following entities:

- Trade Items
- Serialized Trade Items
- Lots
- Serialized Containers
- Events
- Reporting Events
- Business Transactions
- Authentication Requests
- Global Search
- Global History
- Home

#### **General User Interaction and Navigation**

When you select the app *Data Cockpit*, you navigate to the search screen for serialized trade items. You can switch to the other screens by clicking on the screen name in the middle of the title bar. This opens the menu from which you can access the search screens of the other entities, and also *Global Search*, *Global History* and *Home*.

Within a search screen, you can enter the search criteria and by choosing *Go* you obtain your search results. By clicking on the link in the results list, you can navigate to the respective detail screen Alternatively, the detail screen can be accessed directly using the *Global Search* and also through *Global History*. Finally, navigation is also possible between detail screens by clicking an object link within the screen.

#### **Features**

The Data Cockpit app is within the group *SAP Advanced Track and Trace for Pharmaceuticals* . Once you launch the app, the Serialized Trade Item search screen is displayed. The following features help you search for the required objects:

#### Search and Filter

- Use the filter bar to enter the required search criteria and to trigger a smart search of the objects.
- You can choose the option *Filters* to access all search criteria and you can add them also to the filter bar.
- You can choose the options *Show Filter Bar* or *Hide Filter Bar* to show or hide the filter bar. Use *Clear* to clear the values in the search fields.

#### **Global Search**

• Specify the EPC URI ID or the GS1 Element string in the search field of *Global Search* popup to navigate directly to the detailed screen of the selected object. For example, if you search for a SGTIN, then you can give the object ID and the screen navigates directly to the related detail screen.

#### **Global History**

• Displays a list of all UIs and object instances you worked with during your session. You can directly navigate to the UI by clicking on the line.

#### **Export**

• Use the *Export* option to generate an output file of the listed objects.

#### **Detail Screen**

• This screen displays detailed information about the object in a similar way as it is displayed in SAP GUI.

#### Historic Hierarchy

- This displays historic hierarchy data for objects. By using the *Event Slider Bar*, you can display the hierarchy of the object as it was after posting the selected event. You can switch the representation between a hierarchy table and a visual representation.
- You can access the historic hierarchy UI via the detail screen of a serialized container or a serialized trade item by selecting tab *Events* and selecting the hierarchy symbol in the events table (last table column)

### 3.2 Authenticator

Use

With this app, the user can authenticate Serialized Trade Items (SGTINs) or Lots (LGTINs) by scanning the barcode on a medicinal package. The app creates an Authentication Request in the connected SAP Advanced Track and Trace for Pharmaceuticals system. The results of the Authentication Request are displayed in the app. For more information, see Authentication Requests [page 75].

The Authenticator app runs on any iOS/Android/Windows10 device.

#### Features

- Barcode scanner functionality using built-in camera in device
- Decoding of GS1-DataMatrix depending on Application Identifiers configured in SAP Advanced Track and Trace for Pharmaceuticals backend
- Manual input of object code (for example, if barcode is broken)
- Optional transmission of geo location data
- User individual history

### 3.3 Mobile Warehouse

Use

The *Mobile Warehouse* app provides a simplified and compact display of object information (serialized trade items and serialized containers). With the built-in camera of your mobile device you can scan items in the warehouse and check their status, events, transactions and get an idea of how a container is hierarchically packed inside. You can also post event messages for the selected object.

The Mobile Warehouse app runs on any iOS/Android/Windows10 device.

#### **Features**

- Barcode scanner functionality using built-in camera in device
- Decoding of GS1-DataMatrix depending on Application Identifiers configured in SAP Advanced Track and Trace for Pharmaceuticals backend
- Manual input of object code (for example, if barcode is broken)
- Compact display of object information including events, reporting events, business transaction assignment, reporting events, aggregated hierarchy and authentication requests
- Navigation to parent objects in the hierarchy
- User individual history
- Posting of event messages for the selected object via user-specific menu

For the configuration of the user-specific menu for event postings please refer to the chapter *Configure EPCIS* event menus for mobile Warehouse Manager app in the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

### 3.4 Mass Posting

#### Use

The *Mass Posting* app provides an optimized way to post mass events for several objects. The scenario that should be performed must be selected first. Then the built-in camera of your mobile device is called and you can continue scanning barcodes until all relevant objects are collected. After this you can exit the screen and proceed to the next screen for sending the final event.

The Mobile Warehouse app runs on any iOS/Android/Windows10 device.

#### **Features**

- Barcode scanner functionality using built-in camera in the device
- Decoding of GS1-DataMatrix depending on Application Identifiers configured in SAP Advanced Track and Trace for Pharmaceuticals backend
- Manual input of object code (for example, if barcode is broken)
- Mass handling for scanning operations
- Posting of event messages for the selected objects

For the configuration of the user-specific menu, the same transaction as for the Mobile Warehouse app is used. For more information, see the chapter *Configure EPCIS Event Menus for Mobile Warehouse App* in the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

# 4 Country-Specific Features

SAP Advanced Track and Trace for Pharmaceuticals provides country specific functionality and content as part of the country versions provided. This includes amongst others country specific capabilities for regulatory reporting or supply chain reporting, master data and serial number handling and country specific serial number specifications. SAP Advanced Tack and Trace for Pharmaceuticals contains country specific functionality for the following countries:

- Argentina [page 100]
- China [page 109]
- European Union [page 113]
- India [page 127]
- South Korea [page 138]
- Turkey [page 145]
- United States of America [page 146]

### 4.1 Argentina

#### Use

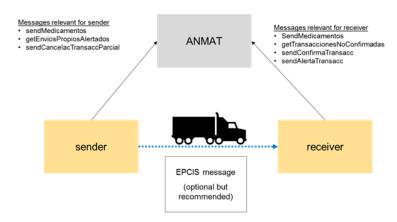
SAP Advanced Track and Trace for Pharmaceuticals supports data exchange with the Argentina ANMAT server.

The following messages are supported

sendMedicamentos	send medicaments
getEnviosPropiosAlertados	get alerted deliveries
sendCancelacTransaccParcial	cancel partial transaction
getTransaccionesNoConfirmadas	get non confirmed transactions
sendConfirmaTransacc	confirm transaction
sendAlertaTransacc	alert transaction

### Integration

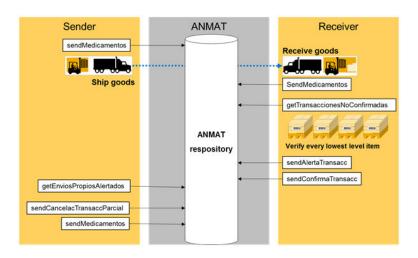
On a high level the message choreography looks as following:



Certain messages are relevant for the sender of the goods and other messages are relevant for the receiver of the goods.

Within SAP Advanced Tack and Trace for Pharmaceuticals regulatory reporting messages typically are triggered during event processing and handled within a rule in the rules framework.

In case of Argentina this is different. Here only the regulatory reporting message *sendMedicamentos* is handled by a rule and triggered from event processing. All the other messages are handled by dedicated transactions because first data needs to be queried from ANMAT server and then compared with data available in the repository and then based on a user decision the regulatory reporting can be triggered. So in this case the trigger is not an event message but a user decision.



#### **More Information**

Regulatory Reporting Messages when Shipping Goods [page 102]

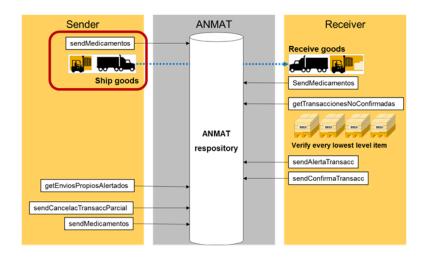
Regulatory Reporting Messages when Receiving Goods [page 107]

Handle Alerted Shipments on Sender Side [page 108]

## 4.1.1 Regulatory Reporting Messages when Shipping Goods

#### Use

When shipping goods to a subsequent supply chain partner then the message sendMedicamentos has to be sent to the ANMAT repository in order to notify ANMAT that the goods are shipped.



SAP Advanced Track and Trace for Pharmaceuticals provides the functionality within rule type RR\_AR\_SEND\_MDC for which adequate rules have to be maintained in the rules definition customizing. For more details see SPRO SAP Implementation Guide SAP Advanced Track and Trace Rules Customizing.

The message sendMedicamentos only contains the lowest level SGTINs and does not contain hierarchies. Therefore it is strongly recommended to additionally send an EPCIS Message including the aggregations of the goods to the receiver of the goods in order to ease logistical processing for the receiver.

One of the specialties of the sendMedicamentos message is that it must contain one of around 500 different event IDs and the challenge is to determine this event ID out of the logistical business context.

#### More Information

Determination of Event ID [page 104]

### 4.1.1.1 Determination of Event ID

#### Use

The event ID determination is a two step process.

- First the event type is determined from customizing /STTP/CUST\_AREVTTYP Define Event Types for Argentina Government
- Based on the sending and receiving business partner the event id can be determined from customizing / STTP/CUST AREVT - Define Event ID for Argentina Government

#### i Note

The content of both tables is delivered as a BC set. You need to import the BC set in order to ensure that the event ID determination works.

#### **Process**

#### **Determination of Event Types**

Certain event types and IDs can be determined based on the existing event parameter.

- AR\_008: DISTRIBUCION DEL PRODUCTO A UN ESLABON POSTERIOR
  - Business step: shipping, sender: business partner with Business Partner Role "Own Organization", receiver: another business partner within Argentina
- AR 033: RECEPCION DE PRODUCTO DESDE UN ESLABON ANTERIOR
  - Business step: receiving, sender: another business partner, receiver: business partner with Business
     Partner Role "Own Organization"
- AR 017: ENVIO TRASLADO ENTRE DEPOSITOS PROPIOS
  - Business step: shipping, sender: business partner with Business Partner Role "Own Organization",
     receiver: business partner with Business Partner Role "Own Organization"
- AR 042: RECEPCION TRASLADO ENTRE DEPOSITOS PROPIOS
  - Business step: receiving, sender: business partner with Business Partner Role "Own Organization", receiver: business partner with Business Partner Role "Own Organization"
- AR 023: PRODUCTO DESTINADO A EXPORTACION
  - Business step: shipping, sender: business partner with Business Partner Role "Own Organization", receiver: another business partner outside Argentina

In order to enable the determination of all event IDs you can provide the extension parameter  $RR\_AR\_EVENT\_TYPE$  within the event extension of the EPCIS message. In this case please provide one of the following event types:

Event Type	Description
AR_001	CODIGO DETERIORADO/DESTRUIDO

Event Type	Description
AR_002	CONTRAMUESTRA DE RETENCION
AR_003	DESTRUCCION DE MEDICAMENTO POR PROHIBICION
AR_004	DESTRUCCION DE MEDICAMENTO POR VENCIMIENTO
AR_005	DESTRUCCION DE PRODUCTO DESTINADO A FINES DE IN- VESTIGACION
AR_006	DEVOLUCION DE PRODUCTO DESTINADO A FINES DE IN- VESTIGACION
AR_007	DISPENSACION DEL PRODUCTO AL PACIENTE
AR_008	DISTRIBUCION DEL PRODUCTO A UN ESLABON POSTE- RIOR
AR_009	ENVIO DE MERCADERIA EN CARACTER DE CUARENTENA
AR_010	ENVIO DE MERCADERIA POR DEVOLUCION EN CARACTER DE CUARENTENA
AR_011	ENVIO DE PRODUCTO DESTINADO A FINES DE INVESTIGA- CION
AR_012	ENVIO DE PRODUCTO EN CARACTER DEVOLUCION
AR_013	ENVIO DE PRODUCTO EN CARACTER DEVOLUCION POR PROHIBICION
AR_014	ENVIO DE PRODUCTO EN CARACTER DEVOLUCION POR VENCIMIENTO
AR_015	ENVIO PARA CONTROL DE CALIDAD
AR_016	ENVIO POR REPOSICION
AR_017	ENVIO TRASLADO ENTRE DEPOSITOS PROPIOS
AR_018	FINALIZAR EMPAQUE POR FRACCIONAMIENTO
AR_019	INICIO DE TRAZA
AR_020	LEVANTAMIENTO DE CUARENTENA
AR_021	MUESTRA MEDICA
AR_022	PRÉSTAMO POR URGENCIA
AR_023	PRODUCTO DESTINADO A EXPORTACION

Event Type	Description
AR_024	PRODUCTO DESTINADO A FINES DE INVESTIGACION
AR_025	PRODUCTO ROBADO/EXTRAVIADO
AR_026	PUESTA EN CONTRAMUESTRA DE RETENCION
AR_027	PUESTA EN CONTROL DE CALIDAD
AR_028	PUESTA EN CUARENTENA
AR_029	RECEPCION DE DEVOLUCION DE PRODUCTO DESTINADO A FINES DE INVESTIGACION
AR_030	RECEPCION DE MERCADERIA EN CARACTER DE CUAREN- TENA
AR_031	RECEPCION DE MERCADERIA POR DEVOLUCION EN CAR- ACTER DE CUARENTENA
AR_032	RECEPCIÓN DE PRÉSTAMO POR URGENCIA
AR_033	RECEPCION DE PRODUCTO DESDE UN ESLABON ANTE- RIOR
AR_034	RECEPCION DE PRODUCTO DESTINADO A FINES DE IN- VESTIGACION
AR_035	RECEPCION DE PRODUCTO EN CARACTER DE DEVOLU- CION
AR_036	RECEPCIÓN DE PRODUCTO EN CARÁCTER DE DEVOLU- CIÓN DESDE EL EXTERIOR
AR_037	RECEPCION DE PRODUCTO EN CARACTER DE DEVOLU- CION POR PROHIBICION
AR_038	RECEPCION DE PRODUCTO EN CARACTER DE DEVOLU- CION POR VENCIMIENTO
AR_039	RECEPCIÓN DE REPOSICIÓN DE PRÉSTAMO POR URGEN- CIA
AR_040	RECEPCION EN CARACTER DE CONTRAMUESTRA DE RE- TENCION
AR_041	RECEPCION PARA CONTROL DE CALIDAD
AR_042	RECEPCION TRASLADO ENTRE DEPOSITOS PROPIOS
AR_043	REPOSICIÓN DE PRÉSTAMO POR URGENCIA

Event Type	Description
AR_044	RETIRO DE MUESTRA POR AUTORIDAD SANITARIA JURIS- DICCIONAL
AR_045	RETIRO DE MUESTRA POR AUTORIDAD SANITARIA. AN- MAT

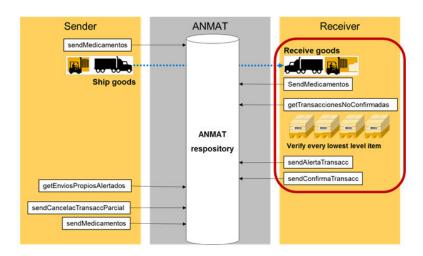
#### **Determination of Event ID**

Event IDs are determined from Event Type, the sending and the receiving business partners (source and destination owning party of the event message). All business partners who participate in the Supply Chain in Argentina therefore need the field business partner category maintained. You need to assign the following business partner categories to your business partners

BP Category	Description
ABFR	BOTIQUIN FARMACIA
ADIS	DISTRIBUIDORA
ADRO	DROGUERIA
AEAS	ESTABLECIMIENTO ASIST.
AEES	ESTABLECIMIENTO ESTATAL
AFAR	FARMACIA
ALMI	LAB. DE MEZCLA INTRAVENOSA
ALAB	LABORATORIO
A3PL	OPERADOR LOGISTICO
APAI	PAIS

# 4.1.2 Regulatory Reporting Messages when Receiving Goods

When receiving goods, the message choreography is more comprehensive.



Upon receiving the goods and the respective event message, one can configure the rules processing to send the regulatory reporting message sendMedicamentos.

Alternatively or in addition SAP Advanced Tack and Trace for Pharmaceuticals offers the transaction /STTP/REP\_AR\_UNC\_TR Handle Unconfirmed Transaction, which enables to query not yet confirmed transactions (outbound delivery or invoice number of sender) from the ANMAT server and to compare it with the data that has been received (inbound delivery). The transaction lists all serialized items coming from the ANMAT server and proposes whether a confirmation shall be sent back to ANMAT for individual items (SendConfirmaTransacc) or whether individual items shall be alerted (sendAlertaTransacc). Per individual item, you can now decide whether to follow the proposal or not and you can now trigger sending the regulatory reporting messages SendConfirmaTransacc and SendAlertaTransacc. When doing so, a reporting event is created just like in any other case when regulatory reporting is executed.

### 4.1.3 Handle Alerted Shipments on Sender Side

On sender's side, periodically it needs to be checked whether one of the receivers alerted some of the goods shipped out. For this purpose, the transaction  $/STTP/REP\_AR\_ALERT$  to Handle Alerted Shipments is provided.

Based on this transaction the sender can query and display the items that have been alerted through sendAlertaTransacc by the receiver of the goods. In case there are any alerted items then the sender needs

to investigate the reason why the item has been alerted and dependent on the root cause the sender needs to notify the ANMAT repository with the adequate message, for example, the individual IDs can be cancelled directly from within the transaction by sending a Regulatory Reporting message

SendCancelacTransaccParcial.

## 4.2 China

#### Use

The country specific functionality for China consists of the following features:

#### **Features**

- Handling of the Chinese Product Master
- Handling of Chinese Serial Numbers
- Regulatory Reporting for China

As of today the data exchange with China CFDA is file based and not service based. The China CFDA offers web pages or a windows application where requests can be made and then in a second step respective data can be uploaded or downloaded from an FTP server. The access to that server is authenticated by a hardware dongle.

China has a completely proprietary system of handling product master data or serial numbers which is not compatible per se with EPCIS. However, in SAP Advanced Track and Trace for Pharmaceuticals the data is setup in a way which allows compatibility with EPCIS and on this basis one can use EPCIS messages to exchange information between supply chain partners. In particular this has the following implications

- The Chinese product master is not an own entity in SAP Advanced Track and Trace for Pharmaceuticals but a trade item (key: GTIN) has to be created and the Chinese product master data is assigned to the trade item
- The Chinese serial number (also China Electronic Drug Monitoring Code (EDMC)) is capable of uniquely identifying an object but in SAP Advanced Track and Trace for Pharmaceuticals, the Chinese serial number is treated just like any other serial number.
- Within SAP Advanced Track and Trace for Pharmaceuticals, Chinese serialized trade items are treated and encoded as SGTINs (GTIN + Serial Number).
  - However, Chinese serialized trade items can be decoded also by the EDMC only. So by scanning an EDMC barcode which only contains the Chinese serial number the serialized trade item can be decoded and identified.

#### i Note

The SAP Advanced Track and Trace for Pharmaceuticals decoder is capable of decoding GS1 element string, EPC URI and EDMC (conditions for identification: 20 digit, numeric, starts with 8).

#### More Information

China Product Master [page 110]

China Serial Number [page 111]

Regulatory Reporting for China [page 112]

## 4.2.1 China Product Master

Although China has a product master data system, the Chinese product master is treated as a trade item in SAP Advanced Track and Trace for Pharmaceuticals.

SAP Advanced Track and Trace for Pharmaceuticals offers the functionality to upload the Chinese Product Master information from a product master XML file to the trade item so that it can be used later on during operational processing like regulatory reporting.

There are two options to upload the product master file. One the one side a mass report pulls and processes all files dropped to a fileshare location mapped to the SAP system. On the other side there is a transaction that allows manual upload of files from local file share locations.

## **Prerequisites for Product Master Upload**

The trade items that shall be enriched with the Chinese Product Master data must exist in SAP Advanced Track and Trace for Pharmaceuticals and per Trade Item the reservation code versions have to be maintained in the following manner on tab time dependent attributes

- Key: CN Value:
- Value: <codeversion> <reservationcode>, for example, 8812345
- Value: <codeversion> <reservationcode> <\_N>, for non-specific resCodes only, for example, 8812345\_1
- Valid from and Valid to

# Upload through Mass Report /STTP/CN\_PRD\_IMPORT – Import Material Master Attributes

- One time setup: A fileshare needs to be configured where the product master files can be managed. Please refer to the Configuration guide for more information.
- The product master files to be uploaded need to be dropped into the upload folder In case the above prerequisites are met then the report can be executed to upload the Chinese Product Attributes to the trade item. Please refer to the report documentation for more details.

# Manual file upload via transaction /STTP/CN\_PRD\_IMP\_LCL - Import Material Master Attributes

Use this transaction to manually select and upload Chinese product master files from a local file share.

The results of the upload can be seen in the Data Cockpit for the trade item on tab Additional attributes. After successful upload per reservation code version a new filter value is added and when selecting the appropriate filter the Chinese product master attributes can be seen.

Furthermore a cleanup report is provided that enables cleaning up old product data that is not needed anymore in the system. The cleanup report can be accessed with transaction /STTP/CN\_CLEANUP Product Master and Serial Number Clean up. Please refer to the report documentation for further details.

## 4.2.2 China Serial Number

SAP Advanced Track and Trace for Pharmaceuticals offers the functionality to upload Chinese Serial Numbers from a serial number flat file to Serial Number Management, so that it can be used for operational processing.

There are two options to upload the serial number file. One the one side a mass report pulls and processes all files dropped to a fileshare location mapped to the SAP system. On the other side there is a transaction that allows manual upload of files from local file share locations.

### Prerequisites for serial number upload

- The trade items have to be set up including the relevant Chinese Product Master data needs to be uploaded to the trade item.
- The trade item must be prepared for serial number management
  - o It must have the profile relevant country "China" assigned.
  - It must have an appropriate serialization profile assigned (for example, SAP CHINA)
  - A range definition must be created for the serialization profile
  - o The product must be active
- Serial number management has to be set up
  - o The range definition must be active

# Upload through mass report STTP/CN\_SNR\_IMPORT – Import Serial Numbers

#### **Prerequisites**

- One time setup: A fileshare needs to be configured where the serial number files can be managed. Please refer to the Configuration guide for more information.
- The serial number files to be uploaded need to be dropped into the upload folder

In case the above prerequisites are met, you can execute the report /STTP/CN\_SNR\_IMPORT Import Serial Numbers to upload the Serial Numbers to Serial Number management. Please refer to the report documentation for more details.

# Manual file upload through transaction /STTP/CN\_SNR\_IMP\_LCL - Import Material Master Attributes

• Use this transaction to manually select and upload Chinese serial number files from a local file share.

Furthermore, a cleanup report is provided that enables cleaning up old serial numbers that are not supposed to be used anymore. You can access the cleanup report with transaction /STTP/CN\_CLEANUP Product Master and Serial Number clean up. Please refer to the report documentation for further details.

# 4.2.3 Regulatory Reporting for China

The regulatory Reporting for China is also file based. So in contrast to reportings for other countries the outcome of the regulatory reporting is an xml file which is stored on a fileshare location and which then has to be uploaded in a separate step to the FTP server offered by CFDA.

The following messages are supported for Chinese Regulatory Reporting:

- Relation Create Message
- Sales Warehouse Out Message
- Purchase Warehouse In Message
- Code Replace Message
- Destroy Warehouse Out Message
- Return Warehouse In Message
- Check Warehouse Out Message

All messages except the code replace message are triggered within event processing and processed as rules during rules processing. As a prerequisite the respective rules have to be configured. A rule type is delivered for each of the supported messages which can be used to configure the rule. For more details please refer to rules processing.

The code replace message is triggered via transaction /STTP/CN\_CODE\_REPL Send Code Replace Message. Please refer to the documentation provided within the program.

# 4.2.4 Scenarios for Specific Drugs in China

In China there are specific setups which require a different handling of the products as well as the serial number. The specific cases which have been addressed as a part of the SAP Advanced Track & Trace for Pharmaceuticals delivery are as follows:

• Handling of non-specific resCodes that must be assigned to more than one GTIN

- Handling of 6 digit resCodes
- Handling of specific file name conventions

The following notes have been released to deliver the required underlying functionality and to provide details on how to set up such specific scenarios within your SAP Advanced Track & Trace for Pharmaceuticals system:

2627649 / China: handling of end-to-end processes for products with non-specific resCodes

2660550 / China SNR uploading: splitting serial numbers for products with non-specific resCodes

2684394 China Reporting: handling files with long names

2724677 China: handling processes for products with 6 digits resCodes

## 4.3 European Union

#### Legislation summary and background information

The European Union introduced anti-counterfeit legislation with the Falsified Medicines Directive (FMD) in 2011. With the release of the Delegated Regulation 2016/161 in February of 2016, the legislation became effective and the regulation has to be complied with by February 2019. The legislation covers serialization and legal reporting as well as the verification at the point-of-dispense.

The European track and trace system will consist of a couple of national repositories and the European Hub that serves as a central entry point and distributes submitted data to the national repositories. Members of the pharmaceutical supply chain can connect either to the European Hub or directly to one or more national systems. The European Hub is provided by the EMVO (European Medicine Verification Organization).

The European Union is introducing an Endpoint Verification System. In this setup, the market authorization holder will have to create a report for all prescription drugs introduced into the European supply chain. All units of these prescription drugs must be serialized using random serial numbers. Within the supply chain regulatory reports are only required for exceptional cases, for example, if a non-authorized wholesaler is handling the goods. Refer to the **Delegated Regulation** for details. At the point of dispense (for example, pharmacy or hospital) the medicament must be verified against the national repository and reported as sold. The system is called Endpoint Verification System because a communication with the European Hub / National Repositories only happens at the end points of the supply chain and not in-between.

# 4.3.1 Country Package European Union

The country specific functionality for the European Union in SAP Advanced Track and Trace for Pharmaceuticals consists of the following features to enable legal reporting through mostly asynchronous web services with the European Hub:

- Establishing connection with the European Hub
- Reporting of product master data
- Reporting of sales packages (create and update)
- Updating of status of sales packages

- Triggering of recall of product batches
- Product Service Subscription and Alerting from Hub
- Verification of product packs

The following services are not yet supported by the solution:

• Request a report and get a report from the European Hub

#### Remarks:

• The country package was specified based on the currently available technical documentation and the currently available implementation of the European Hub provided by EMVO and their providers.

#### i Note

The technical setup for the connectivity and messages exchange with the European Hub system contains several challenges. Therefore please ensure that you follow the configuration guide for European Union for the initial setup as well as for troubleshooting problems. For more information, see the configuration guide for European Union for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>.

# 4.3.1.1 Establishing Connection with the European Hub

The communication with the European Hub is realized through several synchronous web services in most cases.

In principle, there are different possibilities to establish connectivity with the European Hub. They are as follows:

- Direct point-to-point connection between the SAP Advanced Track and Trace for Pharmaceuticals System and the European Hub: This connectivity option is further described in the configuration guide and includes the general connection of the systems through a logical port, and the configuration and scheduling of a report that renews the security session token on a regular basis to retain the right to report to the European Hub.
- To connect the SAP Advanced Track and Trace for Pharmaceuticals System with the European Hub via middleware or a gateway solution: Connectivity needs to be handled within the implementation project in case of middleware or the gateway provider.
- To connect to the European Hub using SAP Information Collaboration Hub for Life Sciences, see the user assistance for SAP Information Collaboration Hub for Life Sciences on the SAP Help Portal at https://help.sap.com/viewer/p/SAP\_INFO\_HUB\_FOR\_LIFE\_SCIENCES\_MAIN.

# 4.3.1.2 Reporting of Product Master Data

As a prerequisite to report sales packages to the European Hub, the corresponding product master data needs to be uploaded beforehand using the asynchronous service *Process Product Master Data*. The message structure contains product related attributes and target market related attributes. For each target market, it is mandatory to report the Marketing Authorization Holder (either with identifier or with full address). Further, all

wholesalers authorized to handle the trade item in this market must be reported as well (also either with identifier or with full address). All wholesalers reported to the European Hub can handle the trade item without verifying the serial numbers against the European Hub / National Repository. Wholesalers not reported must verify every single serial number they handle against the European Hub / National Repository for this trade item.

After submitting the message to the European Hub, the European Hub checks the master data and then distributes it to the national repositories and pushes up to three asynchronous web service response messages back to the submitter based on the processing state.

The following data needs to be maintained at the trade item in order to enable upload of product master data to the European Hub:

- **National Code**: Codes maintained in the field *National Code* for the profile relevant country, or on the tab *Countries* for additional countries, are uploaded as *NationalCode* for the particular target market. The reporting of the national code is currently optional.
- Article 57 Code: Codes maintained in the field *Registration Code* for the profile relevant country, or on tab *Countries* for additional countries, are uploaded as *Article57Code* for the particular target market. The reporting of the Article 57 code is currently optional.
- **Country assignment**: Define profile relevant country and further country assignments for all countries or markets in which the trade item shall be sold.
  - As a prerequisite the countries relevant for the EU Hub reporting need to be maintained in customizing /STTP/EU\_HUB\_COUNTRY Define Countries for European Hub. Only if maintained here those country assignments of the trade item will be reported to the European Hub.
  - o In case you integrate the trade items from SAP ECC then you can maintain country assignments (and also other serialization relevant data) in the new transaction /STTPEC/TRD\_ITM\_SER Maintain trade item serialization attributes.

For more details, see SAP S/4HANA and SAP ECC Add-on for SAP Advanced Track and Trace for Pharmaceuticals [page 169].

- The following specific trade item attributes must be maintained for the trade item on the tab *Additional attributes*:
  - Name (RR\_EU\_NAME)
  - Common Name (RR\_EU\_COMMON\_NAME)
  - Form (RR\_EU\_FORM),
  - Strength (RR\_EU\_STRENGTH),
  - Pack Size (RR\_EU\_PACK\_SIZE),
  - Pack Type (RR\_EU\_PACK\_TYPE)
  - MAH Profile (RR\_EU\_MAH\_PROF)
  - Wholesaler Profile (RR\_EU\_WS\_PROF)
  - → Tip

You can use Assign Country Specific Attributes to assign all needed attributes at once. Furthermore, you can use Check Country Reporting Attributes to verify whether all country specific attributes have been maintained correctly.

#### Remarks

• Prerequisites for maintenance of Form and Pack Type: The permitted values must be maintained in Customizing (Transactions /STTP/EU\_PACK\_TYPE and /STTP/EU\_FORM: From the SAP Menu, go to

# Advanced Track & Trace Repository Customizing Reporting Customizing Europe Reporting Customizing .

- MAH Profile (Marketing Authorization Holder Profile) / Wholesaler Profile:
  - The master data maintenance of Marketing Authorization Holder (MAH) and the list of wholesalers is not done individually for every trade item but within a profile that can be reused across multiple trade items.
  - You need to define and set up one or more profiles for your Marketing Authorization Holder Structures and your Wholesaler Structures in your company. You can now assign the MAH profile and the Wholesaler Profile to your trade item as additional attributes RR\_EU\_MAH\_PROF and RR\_EU\_WS\_PROF. During the reporting of Product Master Data, the MAH and list of wholesalers is determined from the profile.
  - The assignment of the MAH Profile and the Wholesaler Profile to the trade item is optional. If not assigned, the respective Default Profile will be used for the Product Master Data Reporting.
  - Both profiles are maintained in transaction / STTP/EU\_MAH\_WS\_PROF Maintain MAH and Wholesaler Profile. (From the SAP Menu, go to Advanced Track & Trace Repository Data Management Country-specific Functionality Europe .
  - o MAH Profile: For each target market you must report Marketing Authorization Holder Information such as name (mandatory), and either the MAH identifier or the full address. In the profile, you assign the particular business partner which acts as the MAH for the respective country. The actual reporting relevant data is stored at the business partner. If you want to report the optional MAH ID you must maintain a company registration for registration type SAP\_EU\_MAH at the business partner. The MAH name is derived from the attribute *Business Partner Name* and the address data from the business partner address.
  - Wholesaler Profile: For each target market you must report a list of authorized wholesalers with information such as name (mandatory) and either wholesaler identifier or the full address. In the profile, you assign the particular business partner which acts as the wholesaler within the respective country. The actual reporting data is stored at the business partner. If you want to report the optional wholesaler ID you must maintain a company registration for the registration type SAP\_EU\_WS at the business partner. The wholesaler name is derived from the attribute Business Partner Name and the address data from the business partner address.

There are two ways to upload master data to the European Hub:

- Transaction / STTP/EU\_PRD\_MD\_MASS Product Master Data Mass Reporting handles the mass reporting to the European Hub. The report selects all not reported trade items with relevance for reporting to the European Hub, and reports them. You can restrict selection by providing selection criteria to the report. For more information, see the report documentation.
- Transaction / STTP/EU\_PRD\_MD\_DISP Product Master Data Single Reporting enables the selection and display of all trade items relevant for reporting to the European Hub together with their reporting status. Selected trade items can be reported via action Create Product Master Data Reporting. Via this transaction the trade item can be reported multiple times. Every reporting is reflected as a separate line in the result list for the same trade item.
  - Selection Screen: Enables selection of trade items based on the following different selection criteria:
    - o GTIN
    - o Trade item status: Defaulted with active
    - o Reporting Status: Defaulted with not reported
    - Location
    - Countries

- Product Category
- Result List: Displays result of trade item selection.
  - One table line either reflects an unreported trade item or if reported it reflects one reporting event of the trade item. As trade items can be reported multiple times, the same trade item may appear multiple times in the list, every line reflecting one reporting.
  - Most attributes of the result list are common trade item attributes. The following two attributes are specific to the master data reporting: reporting status and reporting date and time Exp. Resp. and Open Resp..
  - Reporting status: The reporting status of a trade item is updated when reporting is submitted to EU hub but also with every asynchronous response from the EU Hub. The reporting statuses are as follows:
    - o 0001 Not Reported: The trade item has not been reported yet to the EU Hub
    - 0002 Reported: The trade item has been reported but no asynchronous response received yet.
    - EU01 EU Hub: VALID: The EU hub has checked the trade item and it is valid (no final status, more asynchronous responses expected)
    - EU02 EU Hub: INVALID: The EU hub has checked the trade item and it is not valid (final status, no more asynchronous responses expected)
    - EU10 EU Hub: LOADED: the EU hub has initiated the distribution and loaded the trade item to the national repositories (no final status, more asynchronous responses expected)
    - EU20 EU Hub: DISTRIBUTED: The distribution of the trade item to the national systems was successful (final status, no more asynchronous responses expected)
    - EU21 EU Hub: DISTRIBUTION FAILED: The distribution of the trade item to the national systems failed (final status, no more asynchronous responses expected)
  - Reporting date and time: Date and time when reporting was triggered.
  - Product Version: The specific product version which was provided within the response from the EU
    Hub. If 20161 is selected in the customizing or if the product was not yet reported via the 20181
    interface, this will be empty. The version can only be filled initially after the response from the EU
    Hub system.
  - o Exp. Resp.: Expected responses from the EU Hub
  - Open Resp.: Still open responses for this specific reporting message

#### Actions

- Show trade item: Navigates to the trade item. If the trade item has not been reported yet, the
  current state of the trade item is displayed, if reporting happened the trade item is shown with key
  date reporting date and time and thus you see the state of the trade item it had when the reporting
  was created.
- *Master Data Reporting:* Opens a drop down to select whether a new product version should be created or whether an existing version should be updated.
  - Create Master Data Reporting: Triggers the trade item reporting for all selected trade items. If needed, the same trade item can be reported multiple times via this transaction. The next reporting however only can be triggered as soon as the previous reporting reached a final status. For every reporting triggered a separate line is shown in the result list for this trade item.
  - Update Master Data Reporting: Triggers an update of the selected trade item version. If needed, the same trade item can be reported and updated multiple times via this transaction. The next reporting however only can be triggered as soon as the previous reporting reached a final status. Also, for every update a separate line is shown in the result list for this trade item, however the product version will remain the same.

#### i Note

Updating a product is only supported since interface version 20181. If version 20161 is set within the Customizing, this functionality is not available and is therefore grayed out.

- o Action Messages AIF: Navigates and displays the message in the AIF monitor.
- Action Messages XML: Displays the outgoing and also asynchronous response message XMLs.
- Both transactions can be found in the SAP Easy Access menu under Advanced Track & Trace
   Repository Data Management Country Specific Functionality
   Europe .

Introduced with Feature Pack 3 there is also a new functionality to withdraw product master data from the European Hub. This functionality is only available if 20181 has been selected as an interface version within the general customizing.

- Transaction / STTP/EU\_PRD\_WITHDR- Product Withdrawal enables the selection and display of all trade items relevant for reporting to the European Hub together with their reporting status. Selected trade items can be withdrawn via action Withdraw Product. As a product withdrawal is an irreversible action within ATTP, a pop-up will be displayed to enter the withdraw effective date and confirm this After selecting to withdraw a product
- Selection Screen: Enables selection of trade items based on the following selection criteria:
  - o GTIN
  - o Trade item status: Defaulted with active
  - o Reporting Status: Defaulted with not reported
  - Location
  - Countries
  - Product Category
- Result List: Displays result of trade item selection.
  - One table line either reflects an unreported trade item or if reported it reflects one reporting event of the trade item. As trade items can be reported multiple times, the same trade item may appear multiple times in the list, every line reflecting one reporting.
  - Most attributes of the result list are common trade item attributes. The following attributes are specific
    to the master data withdrawal: Reporting Status, Reporting Date and Time, Exp. Resp. and Open Resp.
  - Reporting status: The reporting status of a trade item is updated when reporting is submitted to EU
    hub but also with every asynchronous response from the EU Hub. The reporting statuses are as
  - o o 0001 Not Reported: The trade item has not been reported yet to the EU Hub
  - o 0002 Reported: The trade item has been reported but no asynchronous response received yet.
  - EU01 EU Hub: VALID: The EU hub has checked the trade item and it is valid (no final status, more asynchronous responses expected)
  - EU02 EU Hub: INVALID: The EU hub has checked the trade item and it is not valid (final status, no more asynchronous responses expected)
  - EU10 EU Hub: LOADED: the EU hub has initiated the distribution and loaded the trade item to the national repositories (no final status, more asynchronous responses expected)
  - EU20 EU Hub: DISTRIBUTED: The distribution of the trade item to the national systems was successful (final status, no more asynchronous responses expected)
  - • EU21 EU Hub: DISTRIBUTION FAILED: The distribution of the trade item to the national systems failed (final status, no more asynchronous responses expected)
  - Reporting date and time: Date and time when reporting was triggered.

- o Exp. Resp.: Expected responses from the EU Hub
- o Open Resp.: Still open responses for this specific reporting message

#### Actions

- Show trade item: Navigates to the trade item. If the trade item has not been reported yet, the current state of the trade item is displayed, if reporting happened the trade item is shown with key date reporting date and time and thus you see the state of the trade item it had when the reporting was created.
- Withdraw Product: Opens a pop-up to provide additional information and to confirm the withdrawal and for the selected trade items.
- Action Messages AIF: Navigates and displays the message in the AIF monitor.
- Action Messages XML: Displays the outgoing and also asynchronous response message XMLs.
- This transaction can be found in the SAP Easy Access menu under Advanced Track & Trace Repository

  Data Management Country Specific Functionality Europe .

#### Additional information

General customizing parameter RR EU DCT OWN GCP PM

- By default, the Product Master Data reporting to the European Hub checks whether the GTIN reported is an own trade item, or a trade item that belongs to another company. The assumption is that a company only uploads product pack data for own trade items to the European hub. This check is done by verifying whether the GTIN is using a Global Company Prefix (GCP) that is assigned to a business partner which has a role of type own organization.
- With the parameter key RR\_EU\_DCT\_OWN\_GCP\_PM you can deactivate this check which means a reporting to the European hub can be triggered also in case the GTIN is using a GCP of a business partner that is not marked as own organization.

Owner Global Location Number (GLN) concept using Additional Attribute BR\_OWNER\_GLN

- Starting with Feature Pack 3 of SAP Advanced Track & Trace for Pharmaceuticals, as an extension to the check against the Global Company Prefix (GCP), products can be marked with an Owner GLN as an additional attribute on GTIN level. Within the generation of the reporting events, the checking logic is extended to first look up whether an Owner GLN is provided and whether this GLN belongs to a location or business partner of the type Own Organization.
- If the parameter Owner GLN is not provided the checks will apply as before. This means that the GCP check can be activated and only products which fail the GCP check but should still be reported must be marked using this parameter. This reduces the amount of required manual maintenance to exceptional cases such as NTIN based products or products which have been acquired including GTIN.
- This can also be used for the negative case in which the GCP check is passed but the product should not be reported. In such a scenario the Owner GLN of the product must not belong to business partner or location of type Own Organization.

General customizing parameter RR EU INTERFACE VER

- By default, interface version 20161 is selected. This is done to not disrupt existing customer processes. Without setting this parameter or with explicitly setting it to 20161, all reporting messages will be send using the 20161 interfaces and formats, therefore the product master data update as well as the withdrawal are not possible.
- If 20181 is entered the corresponding outbound interfaces are selected and update/withdrawal processes are possible.

# 4.3.1.3 Reporting of Sales Packages (Create)

The sales packages are reported via service *Process Product Pack Data*. Also this process is asynchronous, and also here after sending out the message to the European Hub, up to three asynchronous response web service calls can be received back from the European Hub to provide feedback regarding the status of the asynchronous processing within the EU Hub.

This service supports two methods: *Create* and *Update*. With *Create*, a new batch with new serialized trade items are reported to the EU Hub and with *Update*, the batch can be exchanged for existing serialized trade items. This chapter deals with the method *Create* and the chapter Reporting of Sales Packages (Update) with the method *Update*.

With one *Process Product Pack Data* service call, all serialized trade items for one particular batch can be reported. The message contains, for example, the product code (GTIN), the batch ID, the batch expiry date, the pack size (the same as in master data reporting), and a list of all serial numbers. Furthermore, manufacturer details must be provided such as name (mandatory) and either ID or the full address. The manufacturer details are derived from the business partner which represents the manufacturer. The business partner is determined via the read point GLN of the commissioning event of the serialized trade items to be reported. If you want to report a manufacturer ID, you need to maintain a company registration for the registration type SAP\_EU\_MAN. The substructure *Source Repack Buffer* is not relevant for the method *Create* (For more information on the usage, see Reporting of Sales Packages (Update) [page 122]).

The reporting is triggered via a rule. You can create rules for *Product Pack Data Reporting* by using rule type RR\_EU\_PROD\_PACK\_DATA.

This rule can be triggered from any event message that contains the object IDs to be reported, or their parents if the objects are aggregated.

For the European Union many market authorization holders may decide to go without aggregation and simply serialize the items only. In this case typically the objects are commissioned but no other events are captured. For example, no event is captured for a sales unit upon shipping when a complete shipper cases is being shipped. Therefore the reporting to the European Hub cannot be triggered based on a shipping event. Instead the following options may be considered:

- Trigger reporting with commissioning of objects
- Use transaction /STTP/CREATE\_EPCIS Select objects and trigger EPCIS notification to select objects for example, for a batch or a production order, and compose an internal shipping event that triggers the reporting. For more information, see Outbound Processing [page 89].

For every reporting of sales packages to the EU Hub, a reporting event is created and can be displayed in the data cockpit. In principle this reporting event behaves like any other reporting event. However, due to the asynchronous communication with the European Hub the following specifics apply:

- After successful submission of the web service message to the European Hub the status of the reporting event is set to 1 Sent ok.
- The new attribute *response status* captures the status of the asynchronous responses from the EU hub. The following statuses apply for the reporting of sales packages:
  - o No response: No response received from the EU Hub
  - EU01 EU Hub: VALID: The message has been checked by the EU hub and it is valid (this is not a final status and further responses are expected)
  - EU02 EU Hub: INVALID: The message has been checked by the EU hub and it is invalid (this is a final status and no further responses are expected)

- EU20 EU Hub: DISTRIBUTED: The message has been successfully distributed to all country repositories (this is a final status and no further responses are expected)
- EU21 EU Hub: DISTRIBUTION FAILED: The distribution to the country repositories failed (this is a final status and no further responses are expected)
- When you display the reporting event in the data cockpit or the Web UI, you will find two attributes to help you keep track of all the asynchronous responses. The attribute *Expected Responses* displays the overall number of asynchronous response messages that are expected to be received from the EU Hub. The attribute *Open Responses* shows you the number of response messages that are still open. On the selection screen, you can select the checkbox *Only Open Responses* to display reporting events for which asynchronous response messages are still expected (*Open Responses* >0).
- Via action *Message File* the asynchronous response messages from the EU Hub can be accessed. Especially in case of failed processing the messages contain further information regarding potential processing errors within the EU Hub.

#### Additional information

- Before reporting the sales packages to the European Hub, the product master data must be reported. The solution however cannot make a hard check whether the master data is reported because the company reporting the master data and the sales packages may be different. Please ensure process-wise that master data has been uploaded and distributed to the Hub before reporting sales packages. Otherwise the EU hub will not process your reporting message and return an error message.
- Starting with SAP Advanced Track & Trace for Pharmaceuticals 2.0 FP3 there is no longer a dependency for the reporting on the base unit of measure of a Trade Item. RR\_SAP\_EU\_REPREL was introduced as a specific Additional Attribute which can be used to mark the GTINs relevant for reporting. It is important to assign this attribute to all GTINs belonging to the same material, the relevant unit of measure should be marked with an "X" whilst for the other GTINs the parameter should be set with an empty value.
- General customizing parameter RR\_EU\_DCT\_OWN\_GCP\_PP
  - By default the *Product Pack Data Reporting* checks whether the GTIN reported is an own trade item or a trade item that belongs to another company. The assumption is that a company only uploads product pack data for own trade items to the European hub. This check is done by verifying whether the GTIN is using a Global Company Prefix (GCP) that is assigned to a business partner which has a role of type *own organization*.
  - With the parameter key RR\_EU\_DCT\_OWN\_GCP\_PP you can deactivate this check, which means a reporting to the European hub can be triggered also in case the GTIN is using a GCP of a business partner that is not marked as *own organization*.
- General customizing parameter RR EU BATCH EXP 00
  - The Product Pack Data Reporting sends the Batch information including the manufacturing date. This
    customizing parameter can be used to overwrite the day value within the manufacturing date with 00.
    This is the defined approach from European Hub side to mark products which do not have an explicit
    day within their expiry.

#### 

The barcode which is printed on the sales package contains the batch expiry. If the parameter RR\_EU\_BATCH\_EXP\_00 is set and a product is therefore reported using 00 as a day, a validation of this barcode will fail if the encoded expiry date on the actual sales package is different from the reported expiry within the Product Pack Data Reporting message. We therefore recommend checking whether the process integrity for reporting and validation remains before setting this parameter.

# 4.3.1.4 Reporting of Sales Packages (Update)

This chapter is about the method *Update* of service *Process Product Pack Data*. This service mainly deals with exchanging the batch for items that have been already reported, which is an exceptional scenario. SAP Advanced Track and Trace for Pharmaceuticals supports exchanging the batch for existing trade items by posting a *Transformation Event* with the special business step <code>sap\_assigning\_new\_lot</code>. The rule <code>RR\_EU\_PROD\_PACK\_DATA</code> can detect the use case of exchanging the batch for existing trade items and then posts the service *Process Product Pack Data Update* to the EU hub. For all other details please see Reporting of Sales Packages (Create) [page 120].

# 4.3.1.5 Updating of Status of Sales Packages

When a sales package is reported to the European Hub via service *Process Product Pack Data*, then the status of the item is always *ACTIVE* by default, and with this also valid for sales in a pharmacy, for example. The asynchronous service *Process Product Pack State Update* enables you to change the status of already reported items, to prevent unwanted sales and to declare an item as temporarily "not sellable" or to invalidate ("decommission") the item permanently in the repository. The service offers a couple of pack status types for different business processes. The European Hub in principle supports the following pack status types: *ACTIVE*, *DESTROYED*, *STOLEN*, *SAMPLE*, *FREE SAMPLE*, *SUPPLIED*, *LOCKED*, *EXPORTED*, *CHECKED-OUT*.

#### i Note

The product pack state *RECALLED* is triggered via a separate service (see Triggering the Recall of Product Batches [page 124].

The reporting is triggered via a rule. You can create rules for *Process Product Pack State Update* by using rule type RR EU PROD PACK UPD.

In principle, this rule can be triggered from any event message that contains the object IDs to be reported or their parents if the objects are aggregated. Of course, it only makes sense to trigger this rule for events with certain business steps. If you want to report a decommissioning of a former valid item to the EU Hub, configure a rule with business step *decommissioning*. If you want to report an undo of decommissioning to the EU Hub, configure a rule with business step *sap\_activating*. If you want to report a destruction of an item, configure a rule with business step *destroying*. The rule checks whether the trade item to be reported is relevant for EU Hub reporting via the country assignment. If not relevant, the trade item will be excluded from reporting.

Update: With Note 2536653 a BAdi was provided to enable the setting of the other available statuses based on the content of the triggering EPCIS event. Additionally, an implementation of this Badi was provided within note 2652318 and the corresponding prerequisites.

Currently, SAP Advanced Track and Trace for Pharmaceuticals supports the automatic setting of pack status types for the following event messages:

- In case the triggering event has one of the SAP specific dispositions assigned:
  - If disposition "sap\_eu\_destroyed", the solution can trigger the service Process Product Pack State Update with new pack status "DESTROYED";
  - If disposition "sap\_eu\_sample", the solution can trigger the service Process Product Pack State Update with new pack status "SAMPLE";

- If disposition "sap\_eu\_free\_sample", the solution can trigger the service Process Product Pack State Update with new pack status "FREE SAMPLE";
- If disposition "sap\_eu\_exported", the solution can trigger the service Process Product Pack State
   Update with new pack status "EXPORTED";
- If disposition "sap\_eu\_supplied", the solution can trigger the service Process Product Pack State Update with new pack status "SUPPLIED";
- If disposition "sap\_eu\_locked", the solution can trigger the service Process Product Pack State Update with new pack status "LOCKED";
- If disposition "sap\_eu\_checked\_out", the solution can trigger the service Process Product Pack State
   Update with new pack status "CHECKED\_OUT";
- o If disposition "sap\_stolen", the solution can trigger the service Process Product Pack State Update with new pack status "STOLEN".

#### → Tip

This logic is encapsulated within a default implementation of the BAdI /STTP/BADI\_EU\_PPU\_STATUS\_SET and therefore can be changed if required.

- In case the triggering event has one of the non SAP specific dispositions assigned:
  - o In case of a "decommissioning event", the solution can trigger the service Process Product Pack State Update with new pack status "LOCKED".
  - o In case of a "destruction event", the solution can trigger the service Process Product Pack State Update with new pack status "DESTROYED".
  - Whenever a decommissioned object is activated again via SAP-specific business step "sap\_activating", the solution can trigger the service Process Product Pack State Update with new pack status "ACTIVE".

All other status types are either not relevant for reporting a product pack state update message within SAP Advanced Track and Trace for Pharmaceuticals or they cannot be determined during rules processing because the EPCIS event messages do not contain the necessary context information to determine the respective business processes. A processing via a rule that is always triggered from an event message is not possible.

For every reporting of status update of sales packages to the EU Hub a reporting event is created and can be displayed in the data cockpit. In principle the reporting event for the European Union behaves like any other regulatory reporting event. However, due to the asynchronous communication with the European Hub the following specifics apply:

- After successful submission of the web service message to the European Hub, the status of the reporting event is 1 Sent ok.
- The attribute *response status* captures the status of the asynchronous responses from the EU hub. Following statuses apply for the update of sales packages:
  - o No response: No response received from the EU Hub
  - EU31 EU Hub: SUCCESS: The message has been processed by the EU hub and the status update was successful for all reported items (this is a final status and no further message is expected)
  - EU32 EU Hub: FAIL: The message has been processed by the EU hub and the status update failed for all reported items (this is a final status and no further message is expected)
  - EU33 EU Hub: PARTIAL: The message has been processed by the EU hub and the status update was successful for part of the reported items and failed for the rest of the reported items (this is a final status and no further message is expected)
- When you display the reporting event in the data cockpit or the web UI, you find two attributes that help you in keeping track of all the asynchronous responses. The attribute *Expected Responses* displays the

overall number of asynchronous response messages that are expected to be received from the EU hub. The attribute *Open Responses* shows you the number of response messages that are still open. On the selection screen you can select the checkbox *Only Open Responses* to display reporting events for which asynchronous response messages are still expected (*Open Responses* >0).

• Via action *Message File* the asynchronous response messages from the EU hub can be accessed. Especially in case of failed processing, the messages contain further information regarding potential processing errors within the EU Hub.

#### Additional information

- General customizing parameter RR EU CHECK PPD RESP
  - This parameter is only relevant for the determination of the *Initial Product Pack Status* within the *Product Pack Data Update* message. Via setting this parameter it can be customized whether the response status of a reporting event should be relevant for this determination or not.
  - By default, response statuses are ignored for these purposes. If the parameter is set, only *Product Pack Data Update* messages with the corresponding response status defined within the allowed parameter values are valid for determining the *Initial Product Pack Status*.
  - By default, the Product Pack Data Update to the European hub does not checks whether the GTIN
    reported is an own trade item or a trade item that belongs to another company. The assumption is that
    a company only uploads product pack data for own trade items to the European hub. This check is
    done by verifying whether the GTIN is using a Global Company Prefix (GCP) that is assigned to a
    business partner which has a role of type own organization.
- General customizing parameter RR EU CHECK PPD SENT
  - By default, the *Product Pack Data Update* is send without explicitly checking the whether all the
    included SGTINs have already been reported via a *Product Pack Data* message to the European hub.
    The parameter is used to customize whether *Product Pack Data Update* notification should be sent
    only if preceding *Product Pack Data* notification was sent for all reported serialized Trade Items.
  - Via the parameter values it can be configured to only check whether a *Product Pack Data* message has been sent or to additionally check whether the European hub response status is *DISTRIBUTED*.

# 4.3.1.6 Triggering the Recall of Product Batches

The purpose of the service *Process Product Batch Recall* is to trigger a batch recall to the EU hub and the underlying national systems for product batches that are already reported. Product batches are not reported explicitly through an own reporting message, but implicitly via the service *Process Product Pack Data*.

The batch recall however is not done on a product pack level (serialized trade item level) but for the complete batch via the service *Process Product Batch Recall*. In the case of multi-market packs, the batch recall can be triggered for certain markets only.

The batch recall is a complex business process within the EU hub, where the hub communicates back and forth with the national repositories and also with parallel distributors. After a Marketing Authorization Holder (MAH) requests the batch recall to the EU hub, and the EU hub will provide back multiple asynchronous response (call back) messages.

- Response messages for pre-checks done by the EU hub before initiating the batch recall to the national repositories.
  - Message 1 *Product Batch Recall Status*: One initial response message indicating whether the submitted batch recall request is valid in general.

- Message 2 Product Batch Recall Markets List: If valid, the EU hub will send one response message confirming which of the requested markets the batch recall will be initiated for, and which ones it will not be initiated for.
- Response messages of the batch recall
  - Messages 3-n Product Batch Recall Results: One response message with the summary result from all
    parallel distributors that consumed this batch, and for each market one response message from the
    responsible national repository confirming the success or failure of the batch recall from this national
    system.

In SAP Advanced Track and Trace for Pharmaceuticals the product batch recall can be initiated via the transaction /STTP/EU BTCH RECALL - *Initiate and Report Batch Recall* (From the SAP Menu, go to

Advanced Track & Trace Repository Data Management Country-specific Functionality Europe D. There you need to specify the Global Trade Item Identification Number (GTIN), the lot number and a recall information. In case of multi-market packs, you can recall the batch from dedicated markets by selecting Recall From Dedicated Markets. When executing the report, the solution first checks that the batch has been previously reported via Process Product Pack Data to the European Hub. If so the report composes a recall event message for the batch (LGTIN) and submits it to the event capturing. If the event processing succeeds and the batch (LGTIN) is declared as recalled within the repository, a reporting event is created for the batch (LGTIN), which then composes and sends service Process Product Batch Recall to the EU hub. If this service call succeeds, the batch recall is initiated and now the asynchronous response messages are received from the EU hub.

In principle, the reporting event for the European Union behaves like any other regulatory reporting event. However, due to the asynchronous communication with the European Hub the following specifics apply:

- After successful submission of the web service message to the European Hub, the status of the reporting event is 1 Sent ok.
- When you display the reporting event in the data cockpit or the web UI, you will find two attributes which help you keep track of all the asynchronous responses. The attribute *Expected Responses* displays the overall number of asynchronous response messages which are expected to be received from the EU hub. The attribute *Open Responses* shows you the number of response messages that are still open. On the selection screen, you can select the checkbox *Only Open Responses* to display the reporting events for which asynchronous response messages are still expected (*Open Responses* >0).
- The attribute *Response Status* captures the status of the asynchronous responses from the EU hub. The following statuses apply for the batch recall:
  - *No response*: Initial response status after submitting the message to the EU Hub. No response received from the EU Hub.
  - Response message 1 Product Batch Recall Status leads to one of the following response status values:
    - o EU01 Valid: The message has been checked by the EU Hub and is valid in principle.
    - EU02 Invalid: The message has been checked by the EU Hub and is not valid.
  - Response message 2 Product Batch Recall Markets List leads to one of the following response status values:
    - o EU40 EU Hub: Batch recall initiated for all requested markets
    - EU41 EU Hub: Batch recall initiated for part of the requested markets
    - o EU42 EU Hub: Batch recall initiated for none of the requested markets
  - Response message 3-n Product Batch Recall Results lead to one of the following response status values:
    - o EU33 EU Hub: PARTIAL
      - As long as *Open Responses* >0, the response status is always partial

- When all asynchronous responses are received (*Open Responses* = 0) the status remains partial, if the recall was successful in some of the markets and not successful in other markets.
- So the response status partial needs to be interpreted in combination with the attribute Open Responses and slightly changes the semantics for Open Responses > 0 and Open Responses = 0.
- o EU31 EU Hub: SUCCESS
  - The status *Success* is set only when all expected asynchronous responses are received (*Open Responses* = 0) and the recall was successful in all markets
- o EU32 EU Hub: FAIL
  - The status Fail is set only when all expected asynchronous responses are received Open Responses = 0) and the recall was not successful in all markets
- Via action *Message File*, the asynchronous response messages from the EU hub can be accessed. Especially in case of failed processing, the messages contain further information regarding potential processing errors within the EU Hub.

#### Additional information

General customizing parameter RR EU CHECK PPD RESP

# 4.3.1.7 Product Service Subscription and Alerting from Hub

The European Hub can send product related alerts to the connected parties (in the case of a batch recall, for example). To receive alerts, you first must register (subscribe) by triggering service *Process Product Service Subscription* and by providing a service address to which the alert will be provided.

With SAP Advanced Track and Trace for Pharmaceuticals, you can trigger the service *Process Product Service Subscription* by executing the transaction /STTP/EU\_HUB\_PSR-EU Hub: Product Service Subscription Request (From the SAP Menu, go to Advanced Track & Trace Repository Customizing Reporting Customizing Lurope Reporting Customizing D. This transaction calls the service and submits the defined response URL to the EU Hub. For more information about the functionality and how to configure the response URL, see the report documentation, and the configuration guide for Europe at http://help.sap.com/attp.

Once you successfully subscribe, you can receive alerts from the European Hub. The EU hub submits an Alert Request service call to your SAP Advanced Track and Trace for Pharmaceuticals system. The alerts are received in AIF interface <code>EU\_ALERT</code> (namespace /STTVI). You can use the AIF Alert handling capabilities to notify a user via all means allowed by AIF (for example, via SMS or email) for every alert request submitted from the EU hub. For more information see Usage of AIF Error Handling and Alerting for SAP Advanced Track and Trace for Pharmaceuticals [page 211].

## 4.3.1.8 Product Pack Verification

The European Hub allows the verification of one or more product packages. Starting with SAP Advanced Track and Trace for Pharmaceuticals 2.0, Feature Package 02, the verification against the EU Hub is supported.

Transaction /STTP/EU\_PACK\_VERIFY - *Product Pack Verification* is used as an entry point to trigger such reporting messages. Single objects can be added to a list and the complete list will be used as a basis for reporting.

SAP Advanced Track & Trace for Pharmaceuticals displays whether the entered code is known to the repository. For known content, additional information can be derived such as batch information and expiry date. For validating unknown objects, the complete barcode must be entered including the information about batch and expiry date, for example, (01)18803913900066(21)1000100570(10)TG\_HU003-1(17)181208. Depending on whether these are objects from different batched products, or with different expiry dates, SAP Advanced Track & Trace for Pharmaceuticals will separate the input into one or several reporting messages.

## 4.4 India

India is introducing a track and trace legislation which includes serialization and legal reporting. The introduction will be in different phases. The first phase is already in effect and deals with serialization and legal reporting for export drugs. The second phase is vague at this point in time and it is assumed that it deals with serialization and legal reporting of drugs for the Indian domestic market. The Indian government launched the Drugs Authentication and Verification Application (DAVA) portal for drug authentication and tracking and tracing of the drug supply. The regulatory reporting files must be uploaded to this portal.

The country specific functionality for India in SAP Advanced Track and Trace for Pharmaceuticals focuses on the first introduction phase and consists of the following features:

- Serialization and Aggregation of packaging levels defined by Indian Authorities: Primary, Secondary, Intermediate Secondary Level 2, Intermediate Secondary Level 3, and Tertiary packaging level
- Regulatory Reporting of products manufactured in India and exported to other countries consisting of the following elements
  - Product Details Reporting
  - Batch Details Reporting
  - Production Details Reporting
- The data exchange with the Indian DAVA portal is file based. The reporting functionality creates XML files which are stored on a mapped FileShare and which are then uploaded to the DAVA portal in a separate step.

Summary of Serialization and Bar code requirements

Pack Level	Description	Indicator Digit GTIN	Serialization Mandatory?	Bar code
Tertiary	Most outer packaging level, typically shipper pallet	5	Mandatory: SSCC	Homogenous
				1: GTIN, Expiry, Batch
				2: SSCC
				Heterogenous
				1: SSCC
				India Bar code Manda- tory!
				Plus: bar code of target country if different
Intermediate Secondary level 3	Outermost secondary	3	Optional: SGTIN	GTIN, Expiry, Batch, Serial
				(Exemption possible)
				Plus: bar code of target country if different
Intermediate Secondary level 2	Second level of secondary	2	Optional: SGTIN	GTIN, Expiry, Batch, Serial
				(Exemption possible)
				Plus: bar code of target country if different
Secondary	Package containing the primary	1	Mandatory: SGTIN	GTIN, Expiry, Batch, Serial
				(Exemption possible)
				Plus: bar code of target country if different
Primary	Package in contact with drug	0	Optional: SGTIN (Unclear whether mandatory or optional)	Barcode exempted/ optional for now: GTIN, Expiry, Batch, Serial (Exemption possible) Plus: bar code of target country if different

## i Note

Remark on primary level: Bar code is exempted for now which implies that with this also serialization does not make sense and should be exempted as well. However, it is unclear whether primary needs to be

serialized and reported nonetheless. However, the solution is capable of dealing with both scenarios – primary level being serialized and not.

# 4.4.1 Regulatory Reporting for India

### Use

The regulatory reporting for India consists of the following individual reports, which are currently only valid for drugs exported from India:

- Product Details Reporting
- Batch Details Reporting
- Production Details Reporting

The Regulatory Reporting for India is file based. The output of the reporting are XML files which are stored on a FileShare location and which is mapped to the SAP system. In a separate step the files then have to be uploaded to the DAVA portal using a token or private key that needs to be installed on the hardware that communicates with the portal. As a prerequisite, a one-time registration on the portal must be made.

Please find more information how to setup and connect a file share to the SAP system in the configuration guide.

#### More Information

- Product Details Reporting [page 129]
- Batch Details Reporting [page 133]
- Production Details Reporting [page 135]

# 4.4.1.1 Product Details Reporting

#### Use

In India besides transactional data, the product master data too has to be reported to the DAVA portal. The result of the reporting is a product details XML file which is stored in a FileShare folder mapped to the SAP system. Although product detail reporting also belongs to the regulatory reporting, it is not handled as a reporting event within SAP Advanced Track and Trace. Instead, there is a separate transaction available that enables selection of the relevant trade items to be reported and also capable of displaying all reporting events that occurred. The reporting can be monitored within SAP Application Interface Framework through the interface IN PRDCT D.

The product details XML contains the product master data required by the DAVA portal in order to correctly understand and interpret the subsequent messages triggered by batch details and production details XML. In SAP Advanced Track and Trace, the Indian product master is represented by the GTIN in the base UOM.

The current scope of this feature is that the product details can be uploaded for all trade items manufactured in India and are meant for export. This basically means that all trade items are relevant which have a plant assigned that is located in India and a sales country assigned outside India.

#### Prerequisites for Product Details Upload:

- Trade items relevant to Indian drugs are available
- Master data has been enhanced by including some of the data to be stored as additional attribute
  and in addition by uploading a mandatory product image in the trade item master as described further
  below.

Once the above prerequisites are fulfilled, you can create and upload the Product Details XML.

#### More Information

- Maintaining Additional Attributes and Uploading Product Image [page 130]
- Creating Product Details XML [page 132]

# 4.4.1.1.1 Maintaining Additional Attributes and Uploading Product Image

#### Use

The following attributes have to be maintained on tab *Additional Attributes* for the trade item in base unit of measure:

Property Name	Property Value	Remarks
RR_IN_MANUFACT_CODE	Maintain 10 digit numeric India Manu- Mandatory for product details repo	
	Content: global company prefix plus suffix zeroes till 10 digits	
RR_IN_PRODUCT_NAME	Maintain product brand name (Max char 50)	Optional for product details reporting. If not provided then "-" will be reported
RR_IN_GENERIC_NAME	Maintain generic name (Max char 100)	Optional for product details reporting. If not provided then "-" will be reported

Property Name	Property Value	Remarks
RR_IN_COMPOSITION1	Composition 1-5 belong together. Property value can hold up to char 100. As composition can have up to 500 char you have to split a composition longer than char 100 into the separate fields and the content will be concatenated for reporting. You must fill compositions in right order. First 1, then 2,	Optional for product details reporting. If not provided then "-" will be reported
RR_IN_COMPOSITION2	See above	See above
RR_IN_COMPOSITION3	See above	See above
RR_IN_COMPOSITION4	See above	See above
RR_IN_COMPOSITION5	See above	See above
RR_IN_SCHEDULED	Allowed values: <b>Y</b> or <b>N</b> Add <b>Y</b> if this is a schedule drug and <b>N</b> if this is a non-schedule drug	Mandatory for product details reporting
RR_IN_USAGE	Provide the dosage/usage of the drug (Max char 100)	Optional for product details reporting; if not provided then "-" will be reported.
RR_IN_REMARK	Product related remark (Max char 100)	Optional for product details reporting; if not provided then <blank> value will be reported.</blank>
RR_IN_EXEMPT_CODE	Allowed values  E21: Consignments containing drugs/ devices for export purposes to countries eligible for exemption from barcoding as per rule 21 of "Drugs and Cosmetic Act" with specific notification number.  EME: Consignment from the merchant exporter containing drugs/devices from multiple manufacturers  ELL: Drugs/devices having bar coding as per importing countries bar-coding requirements.	porting [page 135]).

## **Procedure**

## **Uploading Product Image**

A product image has to be uploaded to the trade item in base UoM.

- 1. In the *Advanced Track and Trace Data Cockpit*, select the trade item in base UoM and click the button *Attachments*. The *Attachment* popup appears.
- 2. In the popup, click Create and select the required product image.
- 3. Click *Upload* to upload the product image. **Note**: Ensure the Data Cockpit is in the edit mode to be able to upload attachments.
- 4. In the *Attachments* screen you must add the usage key RR\_IN\_IMG to the attachment as an indicator that this is the image relevant for product details reporting.

#### Use

When assigning the usage key, the file size is checked and an error message appears if the file is bigger than 3kb (according to DAVA, the Product Image must be smaller than 3kb). Upon creation of the product details reporting file, the image is converted into the specified base64 format. In case more than one attachment with the usage key RR IN IMG is added, then the first attachment found by the system is used for reporting.

# 4.4.1.1.2 Creating Product Details XML

#### Use

You can create the Product Details XML in two ways - Explicit Creation and Implicit Creation.

#### **Explicit Creation**

A new report is available on the SAP Easy Access screen under Advanced Track and Trace Repository Data Management Country-specific Functionality India Creation of Product Details XML Alternatively, you can use the transaction /STTP/IN\_PRD\_DETAILS. This screen allows the explicit creation of product details XML for the relevant trade items. The screen consists of a selection pane and a results pane.

Use the selection pane to retrieve the relevant trade items. However, the selection is restricted based on the following conditions to only retrieve the trade items relevant for reporting:

- Only GTINs in base UoM are relevant for selection
- Only trade items that are manufactured in India and are meant to be exported to other countries are relevant for selection

## **Process**

When you choose *Create Product Details XML* button in the results pane, the function is triggered and the product XML files for all handed over trade items is created and stored in the mapped fileshare. An Indian product can be reported multiple times. Every reporting is reflected as a separate line in the report with its individual reporting time that documents date and time of reporting.

#### **Activities**

You can perform the following actions in the result pane:

- Show Trade Items: Select a single item and click this button. The screen navigates to Advanced Track and Trace Data Cockpit Master Data Trade Items, where you can view the trade item and its details.
- Create Product Details XML: You can create the XML file for multiple trade item selections.
- Update Product -> Send Modification: Product details reporting notification will be sent as modification
- Update Product -> Send Withdrawal: Product details reporting notification will be sent as withdrawal
- Update Product -> Send Deletion: Product details reporting notification will be sent as deletion
- Update Product -> Send Re-Activation: Product details reporting notification will be sent as re-activation
- **Message AIF**: Select one or more item and click this button. The screen navigates to the Application Interface Framework and displays the corresponding AIF messages.
- Message XML: Select a single item to view the XML message.

#### i Note

Ensure the trade items are in "Reported" status in order to view Message AIF and Message XML and "Active" status to create product details XML.

#### **Implicit Creation**

In case one of the subsequent messages is created (for example, batch details or production details), it is checked if the product details has already been created. If not, the product details XML is created "implicitly" on the fly. For more information about implicit creation, refer to Batch Details Reporting [page 133] or Production Details Reporting [page 135].

# 4.4.1.2 Batch Details Reporting

#### Use

The result of the batch details reporting is a reporting event and the batch details XML file which is attached to the reporting event and also stored in a fileshare folder mapped to the SAP system. The reporting can be monitored within SAP Application Interface Framework through the interface IN BATCH D.

The Batch Details XML contains information about the batch of drugs produced. The batch report is sent only once for every batch and contains the batch size (number of primary units). Note that you can report multiple batches in one reporting message. Similar to the Product Details XML, the Batch Details can contain data for only one manufacturer code.

You can create the Batch Details XML either explicitly or implicitly.

#### **Checks for Triggering Batch Details XML:**

Check if the Product Details XML is available for all contained trade items. If not, then create the XML file using the **Implicit Creation of Product Details** given in the topic Creating Product Details XML [page 132].

#### **Explicit Creation**

A reporting rule triggers the creation of explicit batch details based on an event message. The rule creates a reporting event with reference to the contained LGTINs (batches). To activate the rule, go to the SAP Easy Access screen and navigate to Advanced Track and Trace Repository Customizing Rule Customizing Define Rules. For more details on how to define rules, refer to Rules Processing [page 87]. In case of a message split, multiple reporting events are created. The message processing is handled within an own AIF outbound interface.

For the explicit creation of batch details XML for the relevant trade items, you can use the report *Creation of Batch Details XML* from the *SAP Easy Access* screen under Advanced Track and Trace Repository Data Management Country-specific Functionality India Alternatively, you can use the transaction /STTP/IN BATCH D GEN.

#### **Prerequisites for Explicit Creation**

- The trade item of the LGTIN is meant for export (GTIN in base UOM of LGTIN has at least one country outside India assigned to it).
- Important: You must ensure that the rule is triggered only for finished and fully confirmed batches. Otherwise, the system reports the wrong batch size. In case this cannot be controlled, then it is recommended to trigger the batch details reporting implicitly through the production details reporting.

For explicit creation through the report, fill all required fields on the UI like GTIN, Lot Number and GLN of Reporting Event and choose *Execute*. The function is triggered and the batch XML file for corresponding LGTIN is created and stored in the mapped fileshare.

#### **Implicit Creation**

You can create Batch Details implicitly from the production details reporting rule in case the production details is created and the corresponding batch details have not yet been created.

#### **Activities**

You can perform the following actions in the result pane of *Reporting Events*:

- Search for the reporting event.
- **Message AIF**: Select one or more item and click this button. The screen navigate to the Application Interface Framework and displays the corresponding AIF messages.
- Message XML: Use the Message XML tab to view the XML message of the selected event.

You can perform the following actions in the UI:

- Use Produced Quantity: Batch Details will be created with the produced quantity of the lot that used
- Use Actual Quantity: Batch Details will be created with the quantity that calculated by counting the corresponding items
- Use Planned Quantity from Production Order: Batch Details will be created with the planned quantity of corresponding production orders that used
- Send Batch Details Deletion: Batch details reporting notification will be sent as Deletion
- Simulation mode: Processing steps like data selection, composing of reporting notifications, are executed in simulation mode with full logging. The logic of files uploading is skipped.
- Save Application Log: Processing of saving application log

#### **Further Information**

Most reporting attributes can be determined automatically from the context. The following elements require further documentation:

- The batch size is calculated from the attribute "Produced Quantity" of the Lot (LGTIN) that corresponds to the trade item in base UoM (typically corresponds to secondary pack level). As the batch size must be reported in the UoM of the primary pack level, it is converted from base UoM to the UoM of the primary pack level.
- The unit price is left blank as of today as the reporting is optional and it is not clear which price to use.
- The attributes "Exemption Notification and Date" and "Country Code for which exemption is taken" are left blank as of today as the reporting is optional and furthermore the content is not clear.
- The status of the batch is defaulted with "A".
- The status of the batch deletion is "D".

# 4.4.1.3 Production Details Reporting

#### Use

The result of the production details reporting is a reporting event and the production details XML file which is attached to the reporting event and also stored in a FileShare folder mapped to the SAP system. The reporting can be monitored within SAP Application Interface Framework through the interface IN PRDCN D.

There are two categories of products in India, exempted and non-exempted products. Hence, the reporting for them is different. Production Details XML file contains the shipped and exported packaging hierarchy of SGTINs and SSCCs in case of non-exempted products and just the shipped SSCCs and some additional information for exempted products.

A reporting rule triggers the creation of the production details. The rule creates a reporting event with reference to the contained objects. To activate the rule, go to the SAP Easy Access screen and navigate to Advanced Track and Trace Repository Customizing Rule Customizing Define Rules. For more details on how to create rules, refer to Rules Processing [page 87]. Currently, the reporting is only relevant for tertiaries and their hierarchies which are produced in India and exported from India. Export can be assumed in the following cases:

- The triggering event has a destination location assigned (event source destination, SD category: destination, SD type: location) and the destination GLN is mapped to a location with an address outside India
- Alternatively, export can be assumed in case the triggering event has a document of type outbound delivery assigned and the destination location GLN of the outbound delivery is mapped to a location with an address outside India
- In case neither of the above is provided, then it cannot be determined if the event deals with export or not. In such a scenario, no reporting event is created and no reporting happens.

#### **Checks for Triggering Production Details XML:**

- Check if the Product Details XML is available for all contained trade items. If not, then create the XML file using the **Implicit Creation of Product Details** given in the topic Product Details Reporting [page 129].
- Check if the Batch Details XML is available for all contained batches. If not, then create the XML file using Implicit Creation of Batch Details given in the topic Batch Details Reporting [page 133]

### **Production Details XML for Non-exempted Products**

The production details reporting XML for non-exempted products contains serialization information of all pack levels that are relevant for Indian Reporting. The hierarchy is composed dynamically dependent on which levels are actually serialized and aggregated.

- A valid hierarchy must contain at least one top level SSCC (representing the tertiary pack level) and one hierarchy level with secondary SGTINs (SGTINs with indicator digit 1).
- All other relevant levels are reported only if they are actually serialized
  - If there are intermediate secondary level 3 SGTINs or intermediate secondary level 2 SGTINs between SSCC and secondary SGTIN they will be reported as well
    - Please note that the intermediate level 3 secondary hierarchy requires intermediate level 2 hierarchy.
  - o If primary SGTINs are available below the secondary SGTIN then they are reported as well.
- If an event contains more than two tertiaries (SSCCs), the reporting hierarchy is grouped by tertiary SSCC within the XML file.
- In case of heterogeneous tertiaries (SSCC that contains more than one trade item), the reporting hierarchy is grouped by Indian Product Code within the XML file.
- The solution also allows additional SSCC levels below the Tertiary SSCC which are simply omitted from reporting.

Following cases lead to a split of the reporting message and also results in a separate reporting event created:

• If the triggering event contains both hierarchies of exempted or non-exempted products

#### i Note

Mixed hierarchies that contain both exempted and non-exempted products are not supported by the solution, because they cannot be reported.

• The triggering event contains hierarchies of trade items (products) which belong to a different manufacturer code.

### **Activities**

You can perform the following actions in the result pane of the Serialized Container Reporting Events tab:

- Search for the reporting event.
- **Message AIF**: Select one or more item and click this button. The screen navigates to the Application Interface Framework and displays the corresponding AIF messages.
- Message XML: Use this tab to view the XML message of the SSCC.

#### i Note

The data displayed in the Production Details XML differs depending upon the pack level and if the product is exempted or non-exempted.

#### Use

#### **Production Details XML for Exempted Products:**

In certain cases, bar coding and data upload of primary and secondary packs can be exempted. In such a scenario, the exporter is required to put a bar code on the Tertiary pack as per Indian standard and upload data on the central DAVA portal using option Upload Type: "TER" (Tertiary Pack only). Bar coding at the Tertiary level packaging will be in addition to bar coding requirement as per importing country, if any. As of today, the exemption is possible in the following cases:

Case	Exemption Code
Consignments containing drugs or devices for export purposes to countries eligible for exemption from bar coding as per rule 21 of "Drugs and Cosmetic Act" with specific notification number.	E21
Merchant exporter's consignment containing drugs or devi- ces from multiple manufacturers	EME
Drugs or devices having bar coding as per importing countries bar coding requirements.	ELL

Exemption codes must be maintained in Customizing table /STTP/IN\_EXEMPT\_CODE - Define Exemption Codes for Indian Government. You can maintain this Customizing via India Reporting Customizing . Go to the SAP Easy Access screen under Advanced Track and Trace Repository Customizing Reporting Customizing Only those exceptions added in customizing can used for reporting (positive list) irrespective of what has been added to the trade item.

In order to declare that a certain product is exempted from bar coding and reporting the property RR\_IN\_EXEMPT\_CODE has to be maintained on tab *Additional Attributes* for the corresponding trade item (GTIN of Base UoM) and one of the valid exemption codes must be maintained there.

Mixed pallets with exempted and non-exempted products are not supported because the reporting files do not support this case. However the triggering event can contain pallets with exempt and other pallets with non-exempted products. In this case, separate reporting events are created and the reporting is split into different files.

#### i Note

**Important prerequisite**: In order to determine that a hierarchy is exempted from production details reporting, it must be serialized and aggregated nonetheless. This is needed out of two reasons

 Secondary SGTIN is needed within the hierarchy to determine that the hierarchy is exempted from reporting. Without this SGTIN, it cannot be determined.
 Hierarchy is required to determine sub-item count which is needed for reporting.

# 4.4.1.3.1 Production Details Withdrawal Reporting

#### Use

The result of the production details withdrawal reporting is a reporting event and the production details withdrawal XML file that is attached to the reporting event and stored in a fileshare folder mapped to the SAP system. The reporting can be monitored within SAP Application Interface Framework through the interface IN\_PRDCN\_W.

The Details XML file contains shipped SSCCs, file names of reported XML and reasons. You can create the production details withdrawal explicitly.

A new report is available on the SAP Easy Access screen under Advanced Track and Trace Repository Data Management Country-specific Functionality India Creation of Production Details Withdrawal XML. Alternatively, you can use the transaction /STTP/IN\_PRDCN\_WDRWL. This report allows the explicit creation of production details withdrawal XML for the relevant SSCC.

#### **Process**

- 1. Enter the valid SSCC and choose *Validate and to object list*. The entry with the SSCC and fields *Filename* and *Reason* is added to object. Make sure the field *Filename* is not empty.
- 2. Select the entry from the object list and choose Send Withdrawal.

The function of uploading will be triggered, and the production withdrawal XML file will be created and stored in the mapped fileshare.

#### **Activities**

You can perform the following actions in the result pane:

- Remove Object: All selected entries will be removed from the object list
- Erase All: All entries will be removed from the object list

## 4.5 South Korea

#### Use

South Korea is introducing a track and trace legislation which includes serialization and legal reporting.

All trade items handled in South Korea are relevant for legal reporting although only a subset is relevant for serialization. In case trade items are not subject to serialization then only batch level (Lot level) information is reported. In case trade items are serialized, then in addition serialization information is reported.

In general, the South Korean approach consists of a comprehensive data exchange across the complete supply chain and different ways of connecting to and exchanging data with the KPIS portal. From a conceptual standpoint, the reporting shall support different business processes like for example, cancellations, return handling, corrections, and so on.

SAP Advanced Track and Trace supports a limited set of the overall concept. The functionality focuses on the main business of pharmaceutical manufacturers and currently supports straight forward processes and manual data upload to the KPIS portal. The solution may be enhanced at a later point in time to add more scenarios, features, and functions.

The country-specific functionality for South Korea consists of the following features:

- Supply Details Reporting (S01) for the following scenarios:
  - Reporting of shipment of goods (supply class 1 release / ship)
  - Reporting of returns for already shipped goods (supply class 2 return)
  - Reporting of disposal (scrapping) for returned goods (supply class 3 discard)
- The following are the main features of Supply Details Reporting:
  - Creation of Master Template raw data in SAP ECC and integration to SAP Advanced Track and Trace system via BAPI
  - Creation of Master Template and Sub Template CSV files within SAP Advanced Track and Trace system and storage on a mapped file share
  - Manual upload of CSV files to KPIS portal or automated upload via customer specific Interface server (with ESB adapter) pulling data from file share

The following functionality is not supported as of today:

- Supply Details Reporting (S01) for exceptional cases: supply classes, 4-modification and 5-cancellation
- Inbound processing of reporting files to receive transfer supply details message (R01) or return detail notification (R03)
- RFID tag data request (S04 & R04)
- Receipts (R02)
- Direct connection to KPIS through ESB adapter as part of SAP Advanced Track and Trace for Pharmaceuticals

#### More Information

Master Template Raw Data Integration with ECC Add-on [page 140]

Regulatory Reporting for South Korea [page 141]

# 4.5.1 Master Template Raw Data Integration with ECC Add-on

The ECC add-on for SAP Advanced Track and Trace for Pharmaceuticals is capable of composing and sending master template raw data to the Advanced Track and Trace system where it is stored in a separate database table and where it is used for consistent creation of master template and sub template.

The master template raw data integration is triggered in case a Goods Issue is posted for an outbound delivery and the outbound delivery is shipped to a business partner located in South Korea. Furthermore the integration also is triggered in case a Goods Receipt is created for a return delivery and the goods are returned from a location in South Korea.

In case of non-split outbound delivery items, the item itself is integrated. In case of split items, only the sub items are integrated.

Prerequisites to enable integration of outbound/return delivery items as master template raw data item:

- The materials in ERP must have the serialization type 1-Lot managed or 3-Serialized and Traced and must be integrated to SAP Advanced Track and Trace as trade items.
- The batches used in the items or sub items must be integrated to SAP Advanced Track and Trace as Lots (LGTINs).

In case the above prerequisites are not met, then no master template raw data is integrated to SAP Advanced Track and Trace and no reporting will be possible for those items.

The master template raw data integration determines as much data as possible from the outbound delivery/ return delivery or the corresponding sales order/return delivery and defaults certain parameter that cannot be determined in a standard way and which can be redefined within a BAdl if wished (please find more information in the configuration guide for South Korea). Following parameters are defaulted:

- KR\_CNTRCT\_TYPE (Contract type): Defaulted with parameter KR\_CNTRCT\_TYPE from *General Customizing*. If not maintained there then defaulted with 1 (private contract). For more information regarding this General Customizing parameter, see the configuration guide for Korea at http://help.sap.com/attp.
- KR\_SUPPLY\_CLASS (Supply Class): In case triggered from outbound delivery defaulted with 1 (*release/ship*) and in case triggered from a return delivery then defaulted with 2 (*return*).
- KR\_SUPPLY\_TYPE (Supply Type): Defaulted with parameter KR\_SUPPLY\_TYPE from *General Customizing*. If not maintained there, then defaulted with 6 (provision to pharmaceutical provider). For more information regarding this General Customizing parameter, see the configuration guide for Korea at http://help.sap.com/attp.
- KR\_SUPPLIER\_TYPE (Supplier Type): Defaulted with parameter KR\_SUPPLIER\_TYPE from *General Customizing*. If not maintained there, then defaulted with 1 (*Manufacturer*). For more information regarding this General Customizing parameter, see the configuration guide for Korea at http://help.sap.com/attp.
- KR RECVR NAME (Receiver Name): default initial as parameter is optional
- KR KD CD NAME (KD code name): default initial as parameter is optional
- KR\_UNIT\_PRICE (unit price incl VAT): unit price calculated from sales order net price multiplied with tax determined from sales order condition

## 4.5.2 Regulatory Reporting for South Korea

#### Use

The regulatory reporting for South Korea supports the creation of the Supply Details Reporting (S01) files.

The Supply Details reporting consists of two files – Master Template and Sub Template. These templates are created together within the SAP Advanced Track and Trace system.

The master template originates from the previously integrated master template raw data integration and contains information on trade item and batch level. The sub template contains serial numbers and aggregation information for the corresponding table line of the master template. In addition, the sub template contains optional RFID information. However: RFID is not supported by the solution. The sub template is filled only if the Trade Items are serialized. The Master and Sub Template are linked through the Sequence Number.

The reporting files are created in CSV format and stored in a mapped FileShare folder. The message processing is handled within an own AIF outbound interface KR SUPPL D (Korea Supply Details Reporting).

You can trigger this report using:

- An event message triggering the South Korea Supply Details Reporting rule within the rules framework
- A mass report that processes all the non-reported master template raw data table entries
- A manual trigger for selected master template raw data items within master template raw data display transaction

#### Prerequisites for successful reporting:

- As the reporting can be triggered from different places and events and as data of different granularity levels is reported together comprehensive consistency checks are done before the reporting is created. Especially in case a trade item is serialized, both master template raw data information and serialized trade item information must be available and consistent (for example, same batch and quantities) in order to enable reporting. In case of any mismatch the reporting cannot be created.
- In order to allow the consistency checks and the data mapping for the reporting, all serialized trade items to be reported must have a document relation to the triggering document (typically an outbound delivery or a return delivery). Such a document relation can be created by e.g. posting a picking or shipping event with document reference for the Serialized Containers (SSCCs) containing the serialized trade items (SGTINs).
- The following attributes have to be maintained on *Additional Attributes* tab for the trade item to be reported:
  - 이 RR\_KR\_CONTAINER\_SIZE: maintain 8 digit numeric value for container size. Attribute is mandatory for Supply Details reporting and will be mapped to attribute #11 package total unit / 포장내총수량 (규격).
- Both the business partner shipping the goods and the business partner receiving the goods must be
  maintained as business partners in the system and the GLNs used in sold from location or sold to location
  of master template raw data entry must be assigned to the business partner. Furthermore, for all business
  partners one valid company registration must be maintained for country South Korea on Company
  Registrations tab.
  - Activities
    - Registration Type: Use an appropriate type, ideally create a dedicated type for South Korea
       Business Registration Number. For more details, see Business Partner [page 17] for more details.
    - Registration ID: Add the 10 digit numeric South Korean Business Registration Number issued by South Korean authorities.

- **Valid from**: Ensure that valid from date is over when the first reporting happens. Reporting will not be successful in case registration is not valid.
- Valid to: Enter valid to date if the registration id shall not be used anymore for reporting.
- Country: Add KR for South Korea.
- o Region: Do not add any region.
- O As an alternative, if you do not work with SAP ECC, the Remote Function Module /STTP/

  KR\_MSTR\_TMPL\_RAW\_MAINT is also capable of accepting the 10-digit supplier business registration number in field sold\_fr\_loc and the 10-digit receiver registration number in field sold\_to\_loc of importing table IT\_MSTR\_TMPL\_RAW\_HEAD. So if you are not working with SAP ECC, you can provide the registration numbers directly.

### More Information

Mass Supply Details Reporting [page 142]

Master Template Raw Data Display [page 143]

Trigger Event Message through Rules Framework [page 144]

# 4.5.2.1 Mass Supply Details Reporting

#### Use

This report allows to select non-reported master template raw data table entries and to trigger mass reporting for them. Supply Details Mass Reporting can be accessed through the SAP Easy Access screen under

| Advanced Track and Trace | Repository Data Management | Country-specific Functionality | South Korea |
| Korea Mass Supply Details Reporting | Alternatively, you can use the transaction /STTP/

KR SPPL DET MS.

#### i Note

You can trigger the creation of supply details reporting only for items that are in the status *Unprocessed*.

#### **Activities**

Execute the report and optionally use the provided selection parameter to generate the *Supply Details Reporting*.

## 4.5.2.2 Master Template Raw Data Display

### Use

This transaction allows to search and display master template raw data entries that have been integrated from SAP ERP or another external system using the BAPI. Within this transaction, you can also create the supply details reporting for selected table lines.

You can access the Master Template Raw Data Display through the SAP Easy Access screen under Advanced

Track and Trace Repository Data Management Country-specific Functionality South Korea

Master Template Raw Data Display

Alternatively, you can use the transaction / STTP/KR MSTR TMP RW.

Execute the transaction and optionally use the provided selection parameter. The results pane displays the items or sub-items of South Korean outbound deliveries. You can then select one or more non-reported line items and create a supply details report for those line items.

#### i Note

You can trigger the creation of supply details reporting only for items that are in the status *Unprocessed*.

#### **Activities**

You can perform the following activities in the result pane:

- Create Supply Details Reporting: Select one or more items and choose this button.
- Message AIF: Select one or more item in the reporting status Reported and choose this button. The screen navigates to the AIF interface and displays the corresponding AIF messages.
- Message CSV: Select one or more items in the reporting status Reported and choose one of the options
  from the drop down menu of the Message CSV button. This button includes a drop down menu with four
  options:
  - Display Master Template CSV: Use this option to display the South Korean Master Template document in a popup. Only within this popup the content of the Master Template is displayed with headers in the logon language of the user. In addition, the Korean headers are displayed in the first table line (can be hidden via action button Hide additional header). Both headers contain the reference numbers used within the KPIS specifications (Form 24-2, Sheet A) to allow visual mapping of the data. However: The final CSV only contains the Korean headers without the reference numbers as specified by KPIS.
  - o Download Master Template CSV: Use this option to download a CSV file of the master template document. This version does not contain any headers but just the data as required by KPIS.
  - Oisplay Sub Template CSV: Use this option to display the South Korean Sub Template document. Only within this popup the content of the Sub Template is displayed with headers in the logon language of the user. In addition, the Korean headers are displayed in the first table line (can be hidden via action button Hide additional header). Both headers contain the reference numbers used within the KPIS specifications (Form 24-2, Sheet A) to allow visual mapping of the data. However: The final CSV only contains the Korean headers without the reference numbers as specified by KPIS.
  - : Use this option to download the CSV file of the sub template document. This version does not contain any headers but just the data as required by KPIS.

## 4.5.2.3 Trigger Event Message through Rules Framework

#### Use

Another mode of creating the master and sub templates is by using a reporting rule that triggers the creation based on an event message. To activate this rule, go to the SAP Easy Access screen under Advanced Track and Trace Repository Customizing Rule Customizing Define Rules. For more details on how to define rules, refer to Rules Processing [page 87].

The rule type RR\_KR\_SUPPLY\_DET handles both the reporting of shipments of goods and returns for already shipped goods and the rule type RR\_KR\_DISPOSE handles the reporting of scrap / disposal for returned goods.

If you wish to trigger reporting via rules then please create appropriate reporting rules using the rule types.

# Specifics For Reporting Of Shipments Of Goods And Returns For Already Shipped Goods

The triggering event message must contain the same document used in the master template raw data as a document reference.

When processing the reporting rule, the master template raw data integration must already be processed before. The rule first checks if there are corresponding master template raw data entries available for the items to be reported. If they are not available, the processing is stopped. If this processing sequence cannot be guaranteed, the recommendation is to trigger the reporting through different means (either manually or through the mass report).

### **Specifics For Reporting Of Scrap/Disposal For Returned Goods**

Reporting of scrap / disposal for returned goods only can be triggered via a rule, as there is no business document for scrapping that results in a master template entry, which can be used as a starting point for the mass report, or the master template raw data display described above. So please configure a rule for business step *decommissioning* using the rule type RR\_KR\_DISPOSE and appropriate location group and country group assignments. The rule first checks whether the triggering event really is an object event with action *Delete*. If not, the rule is not processed. Furthermore, the rule checks whether the reported items have been reported as returned before to KPIS.

### 4.6 Turkey

### Use

SAP Advanced Track and Trace for Pharmaceuticals supports country specific regulatory reporting and communication with the two Turkish Systems ITS and PTS. ITS is the official Track and Trace system. It operates on item level only (no aggregations). ITS is used to collect, track and trace all relevant supply chain events of the single saleable units in the supply chain.

In addition, Turkey offers a second system, called PTS. PTS offers the supply chain partner the possibility to exchange information about transferred hierarchies. Usage of PTS is optional.

Communication with ITS and PTS is done through web service.

### i Note

With SAP Note 2722890 Reporting TR: New version of ITS Services, the latest version of the ITS web services have been enabled. Additionally, the behavior within the production notification was adjusted. Ensure that this note is installed on your system before reporting messages are triggered.

### More Information

Regulatory Reporting to ITS [page 145]

Data Exchange with PTS [page 146]

### 4.6.1 Regulatory Reporting to ITS

The following messages are supported for Regulatory Reporting to Turkish ITS

- Production notification
- Product purchase notification
- Deactivation notification
- Dispatch notification
- Dispatch cancel notification
- Exportation notification
- Product return notification
- Product turnover notification
- Product turnover cancellation notification

All messages are triggered within event processing and processed as rules during rules processing. As a prerequisite the respective rules have to be configured. A rule type is delivered for each of the supported messages which can be used to configure the rule. For more information please refer to Rules Processing.

### 4.6.2 Data Exchange with PTS

The information exchange with PTS is bi-directional. The sender of the goods sends a web message containing the hierarchy data to PTS and the receiver of the goods can query this information from PTS and use it to commission and aggregate the objects in the own repository before receiving them. On this basis the receiver of the goods can just receive the transport package (typically pallet) and declare all contents as received.

### **Sending data to PTS**

Within SAP Advanced Track and Trace for Pharmaceuticals sending data to PTS is handled just like sending regulatory reporting messages to ITS. So also here sending is triggered within event processing and processed as rules during rule processing. As a prerequisite the respective rule has to be configured. The rule type Send package information to Turkey (PTS) is delivered which can be used to configure the rules accordingly. For more information please refer to rules processing.

### **Query information from PTS**

SAP Advanced Track and Trace for Pharmaceuticals offers the transaction /STTP/TR\_TRNF\_RECEIV Receive PTS transfers to query data from PTS. When the report is run it queries the data from PTS and then commissions and aggregates the items within the repository. Please find further information in the documentation provided within the program.

### 4.7 United States of America

### Use

The Drug Supply Chain Security Act (DSCSA) of United States of America has various introduction phases.

The first phase is the Lot level tracking phase and begins 2015 and will last till 2023. Companies participating in the supply chain process have to exchange lot level information in the form of Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS).

November 2017 manufacturers will have to start serializing their pharmaceutical packages but still the data exchange on lot level only is relevant.

Only by November 2023 the members of the supply chain will need to exchange data on serialized item level.

SAP Advanced Track and Trace for Pharmaceuticals plans to support this phased introduction of serialization.

As of today, SAP Advanced Track and Trace for Pharmaceuticals supports the Lot level EPCIS message exchange together with persisting lot like objects and events within the repository system. In addition item based EPCIS message exchange is supported.

The initial implementation is done based on GS1 US Healthcare implementation guideline 1.1. With SAP Advanced Track and Trace for Pharmaceuticals 2.0, Feature Package 02, additionally GS1 US Healthcare implementation guideline 1.2 is supported.

Lot and Item level ASNs are not supported.

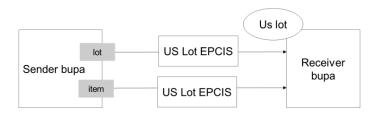
### Specifics for Outbound Message Creation (Sending US Lot or Item Level EPCIS)

Both item and lot level EPCIS outbound message are triggered from the same rule SR\_INFORM\_SUCC (Supply Chain Partner Reporting: Inform Successor) within the rules processing. In case the rule is triggered, it first determines whether and which profile is maintained on the receiving business partner. As part of the profile maintenance, the following Notification Formats can be maintained for the receiving business partner:

- EPCIS: plain EPCIS outbound message according to EPCIS 1.1 without any country specifics
- US Lot: US lot level EPCIS message according to GS1 U.S. Healthcare implementation guideline 1.1
- US Lot: US lot level EPCIS message according to GS1 U.S. Healthcare implementation guideline 1.2
- US Item: US item level EPCIS message according to GS1 U.S. Healthcare implementation guideline 1.1
- US Item: US item level EPCIS message according to GS1 U.S. Healthcare implementation guideline 1.2

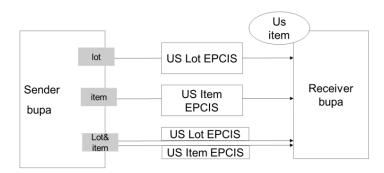
The receiving business partner is determined either through the event source / destination attribute destination owning party or through the sold to GLN of the outbound delivery assigned to the event which triggered the rule.

In case a receiving business partner has the Notification Format US lot, then this business partner gets US lot level EPCIS (Lot DSCSA) messages irrespective of whether the trade item is serialized or lot managed at the side of the sending business partner:



In case a receiving business partner has the Notification Format US Item then this business partner will get US item level EPCIS (Item DSCSA) messages in case the trade item is serialized. However in case the trade item is lot managed and not serialized then the receiving business partner will get US lot level EPCIS (Lot DSCSA) messages. In case the sending business partner is shipping a pallet with both serialized and lot level items then

the receiving business partner will get two EPCIS messages, one containing the US lot level messages and one containing the US Item level messages.



### Specifics for Inbound Message Processing (Receiving US Lot or Item Level EPCIS)

For inbound processing of the special U.S. tags the country content for U.S. has to be activated by adding the country US in the customizing Transaction  $/STTP/C\_CTY\_DM - Country Content Activation$ .

### **More Information**

Lot DSCSA [page 148]

Item DSCSA [page 151]

### 4.7.1 Lot DSCSA

### Use

This feature provides an ability to send and receive EPCIS-Like Lot-Level message containing the Transaction Information, Transaction History, and Transaction Statement. The implementation supports GS1 U.S. Healthcare implementation guideline 1.1. and GS1 U.S. Healthcare implementation guideline 1.2.

Following types are supported:

Message from Manufacturer to First Wholesaler

Sender Side (Manufacturer)

- Prerequisites
  - o LGTIN quantity must be aggregated to SSCCs to know quantity shipped
  - Shipping event for SSCCs
     Further prerequisites given below:
- Outgoing lot level EPCIS message with following specific elements:
  - GS1USHC specific header and master data (including trade item and business partner master data for manufacturer and first wholesaler)
  - One object event with business step shipping for LGTIN (SSCCs are not contained in Message)
    - o Event date: shipping date and time
    - Quantity list filled with LGTIN in EPC URI and quantity shipped
    - Source or Destination List
       Source: GLN of own business partner of Manufacturer
       Destination: GLN of receiving business partner (Wholesaler)

### Receiver Side (First Wholesaler)

- Lot level EPCIS message is processed
  - LGTIN is created based on shipping event from manufacturer
  - Remark: as there is no inventory management done for LGTINs the quantity within the message is neglected. It is stored within the message XML though.

### i Note

As there is no inventory management done for LGTINs, the quantity within the message is neglected. It is stored within the message XML though.

### Message from First Wholesaler to Subsequent Business Partner in Supply Chain

#### Sender Side

### Prerequisites

- LGTIN quantity must be aggregated to SSCCs to know quantity shipped
- Shipping event for SSCCs Further prerequisites given below:

Outgoing lot level EPCIS message with following specific elements

- GS1USHC specific header and master data (including trade item and business partner master data.
   Business partner master data also contains the sending and receiving business partner and in addition all business partners that ever delivered or supplied the product batch and which are referred to in the transaction history below).
- Object events "n" with business step shipping for LGTIN (SSCCs are not contained in Message)
  - Transaction History: Object event 1-(n-1): shipping from supplying business partners to Wholesaler
    - o Event date: 01.01.1970
    - Quantity list filled with LGTIN in EPC URI and quantity shipped
    - o Source or Destination List
      - Source: GLN of supplying business partner
      - Destination: GLN of own business partner of wholesaler
  - Object event "n": shipping from Wholesaler to receiving business partner
    - o Event date: shipping date and time
    - Quantity list filled with LGTIN in EPC URI and quantity shipped

Source or Destination list
 Source: GLN of own business partner of wholesaler
 Destination: GLN of receiving business partner

### Receiver side (First Wholesaler)

- Lot level EPCIS message is processed
  - LGTIN is created based on shipping event from sender

### i Note

As there is no inventory management done for LGTINs, the quantity within the message is neglected. It is stored within the message XML though.

### **Further Notes and Prerequisites**

- The EPCIS Lot message can be configured by creating rules that use rule type SR\_INFORM\_SUCC: Supply Chain Partner: Inform Successor. Please use only this rule type for creating rules for business step shipping as all relevant information is available only in this context.
- Furthermore, please ensure that the shipping event contains a source and destination owning party.
- The sending supply chain partners must be maintained as business partner in the system and the address must be fully maintained.
- The receiving supply chain partner must be maintained as business partner in the system. The address must be fully maintained and this business partner must have the notification format US Lot assigned and a notification system must be maintained capable of receiving the web service.
- Furthermore, the following attributes have to be maintained at the trade item for a successful reporting:
  - Tab Details
    - o National Trade Item Code
    - National Trade Item Code Type
  - Tab Additional Attributes

SC_US_STRENGTH	Supply Chain US HC: Strength
SC_US_MANUFACT_NAME	Supply Chain US HC: Manufacturer name
SC_US_DRUG_NAME	Supply Chain US HC: Drug name
SC_US_DOSAGE_FORM	Supply Chain US HC: Dosage form
SC_US_CONTAINER_SIZE	Supply Chain US HC: Container Size

### More Information

For more information about Lot level tracking, see Lot [page 62].

### 4.7.2 Item DSCSA

This feature provides an ability to send and receive item level EPCIS event messages. The implementation is based on the GS1 U.S. Healthcare implementation guideline 1.1 and GS1 U.S. Healthcare implementation guideline 1.2.

## Sender side: Compose and send an Item Level EPCIS event message that contains of the following elements:

- N commissioning events for all objects contained in the shipped hierarchy with following specifics
  - Event time reflects original time of commissioning event, thus leading to a split of commissioning events in case the event time differs for same objects
  - The <extension> tag contains an <ILMD> tag with GS1 U.S. Healthcare specific trade item master data and lot data information. Trade item master data is derived from trade item additional attributes (given below) and lot information from the lot assigned to the reported serialized trade items.
- M aggregation events that compose the shipped hierarchy with the following specifics
  - Event time reflects the time of the shipping event as the aggregation events of the shipped hierarchy are calculated as if the aggregation happened just before the shipping.
- One shipping event that contains the shipped objects with the following specifics:
  - GS1 U.S. Healthcare specific company master data for the source owning party (sold from business partner) and the destination owning party (sold to business partner)
  - o GS1 U.S. Healthcare specific source license list for source and target location states

## Receiver side: Process an incoming Item Level EPCIS message that contains the above mentioned U.S. Healthcare specifics:

- Commissioning events
  - The lot information of the ILMD tag is interpreted and the corresponding LGTIN is either created or just the reference between the serialized trade items (SGTINs) and the LGTIN is created.
  - The trade item master data information is not processed within standard event processing. However, the respective tags can be made available to the event processing, if required as a blob and processed there within one of the existing BAdIs.
- Aggregation events
  - No specifics
- Shipping events
  - The company master data and the source license list is not processed within standard event processing. However, the respective tags can be made available to the event processing, if required, as a blob and processed there within one of the existing BAdls.

### **Further Notes and Prerequisites**

- The EPCIS Item message can be configured by creating rules that use rule type SR\_INFORM\_SUCC: Supply Chain Partner: Inform Successor. Please only use this rule type for create rules for business step shipping as only in this context all relevant information is available
- Furthermore, please ensure that the shipping event contains a source and destination owning party.
- The sending supply chain partners must be maintained as business partner in the system and the address must be fully maintained. In case the business partner has state licenses assigned for the ship from location and the ship to location then these state licenses will be used as source license list during reporting.
- The receiving supply chain partner must be maintained as business partner in the system. The address must be fully maintained and this business partner must have the notification format US Item assigned and a notification system must be maintained capable of receiving the web service.
- Furthermore the following attributes have to be maintained at the trade item for a successful reporting:
  - o Tab Details
    - National Trade Item Code
    - National Trade Item Code Type
  - Tab Additional Attributes

SC_US_STRENGTH	Supply Chain US HC: Strength
SC_US_MANUFACT_NAME	Supply Chain US HC: Manufacturer name
SC_US_DRUG_NAME	Supply Chain US HC: Drug name
SC_US_DOSAGE_FORM	Supply Chain US HC: Dosage form
SC_US_CONTAINER_SIZE	Supply Chain US HC: Container Size

### 4.8 Russia

### Use

In the beginning of 2017, the Chairman of the Government of the Russian Federation signed a decree on conducting an experiment on marking drugs with control (identification) signs, and monitoring the turnover of certain types of medicinal products for medical use. As a result of the experiment, a system for monitoring the movement of medicinal drugs use has been developed. Reporting to this system will become mandatory during 2018 for certain products, and starting January first 2020, it will cover all available drugs within the Russian market.

With SAP Advanced Track and Trace for Pharmaceuticals, SAP delivers a solution to enable this reporting for marketing authorization holders as well as distributors within the Russian market.

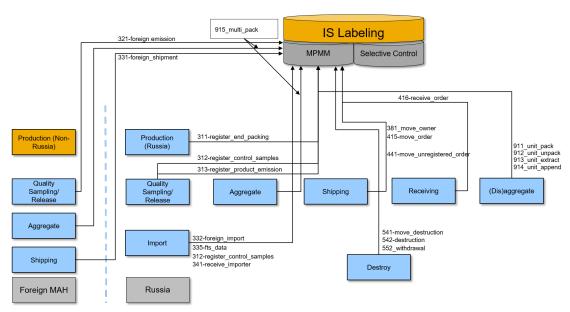
SAP Advanced Track and Trace for Pharmaceuticals includes country-specific content mainly driven by the legislation within the respective country. This includes country-specific interfaces for communicating with governmental systems or supply chain partners, but it also includes certain additional master data or event properties, as well as the related customizing settings.

The country-specific functionality for Russia consists of the following features:

- Handling of Russia product and business partner master
- Regulatory reporting for Russia
- UI for generating Regulatory Reporting message for Russia

### Scope

As Russian requirement specifications are not yet final, SAP is delivering the country package for Russia with initial content.



Reporting Messages for Russia

Here is a list of included messages:

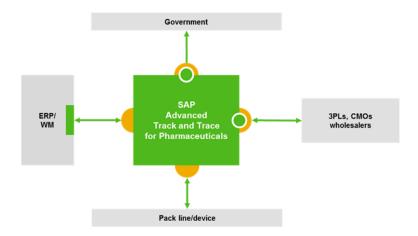
- 311-register\_end\_packing
- 312-register\_control\_samples
- 313-register\_product\_emission
- 321-foreign\_emission
- 331-foreign\_shipment
- 332-foreign\_import
- 335-fts\_data
- 341-receive\_importer
- 381-move\_owner

- 415-move\_order
- 416-receive\_order
- 441-move\_unregistered\_order
- 541-move\_destruction
- 542-destruction
- 552-withdrawal
- 911-unit\_pack
- 912-unit\_unpack
- 913-unit\_extract
- 914-unit\_append
- 915-multi\_pack

### 5 Deployment Models

### **Definition**

SAP Advanced Track and Trace for Pharmaceuticals supports different deployment models. The recommended deployment is to have one Central Repository System only and connect all external systems directly to this one central repository.



### Use

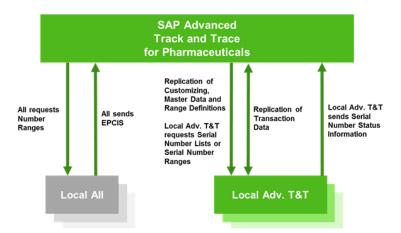
Besides this SAP Advanced Track and Trace for Pharmaceuticals supports the following alternative deployment models:

- Mixed deployment with one Central SAP Advanced Track and Trace for Pharmaceuticals Instance and one or more local Auto-ID Infrastructure (AII) Instances
- Distributed deployment of one Central SAP Advanced Track and Trace for Pharmaceuticals Instance and one or more local SAP Advanced Track and Trace for Pharmaceuticals Instances

In case of mixed or distributed deployment the external systems can be connected either to the Central Advanced Track and Trace Instance or to the Local All Instances or the Local SAP Advanced Track and Trace for Pharmaceuticals Instances dependent on where the actual execution takes place. Government reporting however can be done only from the central instance. The necessary transactional data therefore needs to be replicated to the central instance.

### Integration

The Integration between Central SAP Advanced Track and Trace for Pharmaceuticals and Local SAP Advanced Track and Trace for Pharmaceuticals Instances is much more comprehensive compared to the Integration with Local Alls.



### More Information

Mixed Deployment [page 157]

Distributed Deployment [page 157]

### 5.1 Mixed Deployment

### Use

Mixed Deployment with One Central SAP Advanced Track and Trace for Pharmaceuticals Instance and One or More Local Auto-ID Infrastructure (All) Instances

### Integration

The integration includes the following limited capabilities

### Serial Number Ranges

The local All instances can request serial number ranges from the Central SAP Advanced Track and Trace for Pharmaceuticals instance and handle them just like they were distributed from a central All/OER instance. From Central SAP Advanced Track and Trace for Pharmaceuticals point of view the Local All is treated as a consumer of serial numbers identified by a system ID. Therefore within the Central SAP Advanced Track and Trace for Pharmaceuticals a system needs to be created which represents the local All. Whenever the local All requests a number range it needs to do this request with the system id in order to map this range request to the local All.

### • EPCIS Event Messages

All is able to create and publish EPCIS event messages based on rules to SAP OER. SAP Advanced Track and Trace for Pharmaceuticals is capable of processing EPCIS event messages.

### 5.2 Distributed Deployment

### Use

Distributed deployment of one Central SAP Advanced Track and Trace for Pharmaceuticals Instance and one or more local SAP Advanced Track and Trace for Pharmaceuticals Instances

After setting up the landscape by defining your local instances, you have to replicate the Customizing and master data from the central to the local systems. You have to also configure the replication of transactional data in the rules maintenance in all your systems.

Now, within the local instances, you can start requesting serial numbers and ranges from the central instance, and use those numbers to respond to serial number requests issued to the local system (for example, those coming from a production line connected to the local system or from a CMO connected to the local system).

After production, the line can send EPCIS (or PML) messages to the local system where the messages are processed. Now further logistics events can be captured in the local system (for example, receiving, storing, picking, shipping). At the configured events (typically shipping), the data is replicated to the central instance via the replication rule. There, for example, regulatory reporting is triggered (if relevant). And if relevant, the data is replicated to other local systems if the ship to location is under the responsibility of another local

system. If there is an issue during replication of data, the replication message is introduced either in an outbound replication queue or an inbound replication queue (depending on the error type). Moreover, an error message is introduced into a dedicated AIF interface which can be used as a trigger to alert a user about the integration error.

### Integration

The integration between the central SAP Advanced Track and Trace for Pharmaceuticals and local SAP Advanced Track and Trace for Pharmaceuticals instances is much more comprehensive compared to the integration with SAP Advanced Track and Trace for Pharmaceuticals and local Alls described in chapter Mixed Deployment [page 157].

A crucial part in data replication between central and local SAP Advanced Track and Trace for Pharmaceuticals instances is to define the responsibilities of the central and local instances. This assignment of responsibilities is done in the central SAP Advanced Track and Trace for Pharmaceuticals instance by assigning plant locations to the master data object system representing the local SAP Advanced Track and Trace for Pharmaceuticals instance. As a prerequisite, you have to define a master data object system for all local SAP Advanced Track and Trace for Pharmaceuticals instances. All plant locations known to the central instance and not assigned to a local instance are automatically under the responsibility of the central instance. You can define this in transaction /STTP/DISTR\_LANDSC - Local System Landscape Configuration, where you can also trigger the replication of Customizing, master data and transactional data especially if you initially set up a new system constellation, or if you changed the responsibility between your local instances. If the responsibilities in the landscape did not change, then the normal reports for replication of Customizing and master data and the rule to replicate transactional data shall be used as described below. For more information, see the report documentation.

Furthermore, you can display and review the currently valid assignment of plant locations to local instances in transaction /STTP/CSYST\_LOC - Display Location Assignment to Local Systems. Both transactions can be found in the SAP Menu, under Advanced Track and Trace Repository Customizing System Customizing Local Systems.

The integration includes the following capabilities:

- Replication of Customizing [page 158]
- Replication of Master Data [page 159]
- Replication of Transactional Data [page 162]
- Deployment of Central and Local Instances [page 163]

### 5.2.1 Replication of Customizing

Central and Local Advanced Track and Trace instances must have an aligned customizing in order to allow seamless data exchange. Therefore the report /STTP/DISTR\_CUST Replication of Customizing handles the replication of customizing from the Central SAP Advanced Track and Trace for Pharmaceuticals instance to the Local Instances. The customizing tables relevant for replication are documented in table /STTP/REPL\_CUST. As it is a table with delivery class "S" (system table), the content will be delivered together with the solution.

### 5.2.2 Replication of Master Data

### Integration

Master data which is needed in all SAP Advanced Track and Trace for Pharmaceuticals instances must be created in the Central Instance and then is replicated to the relevant Local Instances. Replication can be done either online or through a report. Furthermore, you can trigger replication of master data when setting up or changing your distribution landscape.

### i Note

Online replication can be configured in general customizing. For more information, see the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>. The report for master data replication can be accessed under /STTP/DISTR\_MD Replication of Master Data.

If a master data object has been replicated from a central instance, it carries a *Replicated* indicator in the local system. Entities with the *Replicated* indicator set cannot be changed. In other words, master data typically is maintained and changed in the central system and then replicated to the relevant local instances where the data is read-only, and can be just used as is.

Within local instances master data can be created locally as well but it cannot be replicated to other instances. Master data can be only changed within the instance where it has been initially created (typically the central instance). Transactional data created for locally created master data objects is under the responsibility of the local SAP Advanced Track and Trace for Pharmaceuticals instance and will not be replicated to the central instance. This also means that such goods can never be exchanged with the central instance or other local instances. Moreover, no regulatory reporting can be done as this is only done from the central instance.

The following master data objects are replicated:

- Business Partners
- Locations
- Trade Items
- Systems

In case of issues during replication (for example inactive or system connection unavailable) the replication data is written into a replication queue either in the sending system (for example, no connection) or in the receiving system and alerts are created in AIF interfaces DISTR\_IN or DISTR\_OUT (both namespace /STTDI). The user responsible can be alerted via AIF capabilities and can resolve the root cause, and then restart the queue. For more information, see Queue Mechanism for Replication [page 164].

### **More Information**

Replication of Business Partner [page 160]

Replication of Locations [page 161]

Replication of Systems [page 162]

Replication of Trade Items [page 161]

### **5.2.2.1** Replication of Business Partner

### Use

Business Partners are replicated to the relevant Local Instances.

### **Process**

By default all business partners within a Central SAP Advanced Track and Trace for Pharmaceuticals Instance are replicated to all Local Instances. You can filter the replication based on a BAdl.

In case of replication of active business partners, potentially assigned range definitions for SSCCs are additionally selected and replicated to the respective local SAP Advanced Track and Trace for Pharmaceuticals instance.

### i Note

Replicated range definitions will carry the Range Definition Origin External. This means that within the Local Instance you cannot work with the range definition in the same way like in the central instance. The central instance is owning the range definition and basically it distributes data to the local range definition on request. So within the local range definition you will have to do either a serial number range request or a serial number list request to the central instance.

### Example

In case of range definitions for SSCCs, which are typically numeric and non-randomized, a range definition with origin external is created and in addition one range in status protected with range type range managed is created. Range type range managed means that this range is only capable of dealing with ranges and not with serial numbers. Status protected means that the range cannot be manipulated within this system. A protected range neither can be used productively nor it can be split etc. The only thing that can be done is requesting a range from the Central Instance. The Central Instance now provides a range which is added below the range definition by splitting the protected range and inserting the supplied range in status created. This range now can be manipulated (e.g. split, assign systems etc) and it can be set to active to be used productively.

In addition the Business Partner Replication also handles the replication of the Global Company Prefixes (GCPs). In case the Business Partner is integrated via the master data replication report then all GCPs are transferred. In case the Business Partner is integrated online then only the GCPs of the particular Business Partner are integrated.

### i Note

Please run the master data integration report regularly for business partners to ensure that all needed GCPs are replicated to the Local Instances.

### 5.2.2.2 Replication of Locations

### Use

Locations are replicated to the relevant Local Instances.

### **Process**

As mentioned in the previous topic, a Local Instance is responsible for one or more plant level locations and their sub-locations. This definition is done by assigning one or more plant level locations to the Local Instance within the Customizing activity /STTP/DISTR\_LANDSC - Local System Landscape Configuration and the current setup can be displayed via transaction /STTP/CSYST LOC Location Assignment to Local Systems.

By default all locations within a Central SAP Advanced Track and Trace for Pharmaceuticals Instance are replicated to all Local Instances. You can filter the replication based on a BAdl.

### 5.2.2.3 Replication of Trade Items

### Use

Trade items are replicated to the relevant Local Instances.

#### **Process**

As mentioned in the previous topic, a Local Instance is responsible for one or more plant level locations and their sub-locations. This definition is done by assigning one or more plant level locations to the local instance in the Customizing activity /STTP/DISTR\_LANDSC - Local System Landscape Configuration and the current setup can be displayed via transaction /STTP/CSYST Loc Location Assignment to Local Systems.

By default all trade items within a Central SAP Advanced Track and Trace for Pharmaceuticals Instance are replicated to all Local Instances. You can filter the replication based on a BAdl.

In case of replication of active trade items, potentially assigned range definitions are also replicated to the respective local instance .

### i Note

Replicated range definitions will carry the Range Definition Origin *External*. This means that within the Local Instance you cannot work with the range definition in the same way like in the central instance. The central instance owns the range definition and basically it replicates data to the local range definition on request. So within the local range definition you will have to do either a range request or a list request to the central instance which depends on the range type of the underlying range created. In case of range type range

managed (only relevant in case range definitions which are numeric and non-randomized) a range request has to be made and in case of range type list managed a list request has to be made.

### 5.2.2.4 Replication of Systems

### Use

The details of Replication of Systems are given below.

#### **Process**

By default all systems within a Central SAP Advanced Track and Trace for Pharmaceuticals Instance are replicated to all Local Instances. The only exception: the system corresponding to a Local Instance is not replicated to that Local Instance. You can filter the replication based on a BAdl.

### 5.2.3 Replication of Transactional Data

In case SAP Advanced Track and Trace for Pharmaceuticals is run within a distributed landscape, transactional data needs to be replicated between these instances in order to support cross location logistics processes.

At one point in time only one instance has control over a serialized object. Within this instance the object will have the status active and events can be received for these object. Other instances may know the object but will not accept any events for this object as the object status is visible (read only) there.

The control over an object instance is managed via the current business location of the object. Whenever an event is processed it is checked whether the business location of the object changed to a location which is managed by another instance and if so the object is replicated to the other instance and the responsibility to change the object is transferred as well to the other instance. This means that in the source instance the object status will change to visible (read only) and in the target instance the objects will be created in status active. When handing over responsibility from one local instance to another local instance this is always done via the central instance.

The data replication is triggered and managed via the rules framework just like for any other outbound communication. The rule type <code>BR\_DISTR\_DM</code> handles the replication. So the trigger for the replication always is an event.

In case of issues during replication (for example, master data object unknown or inactive or system connection unavailable), the sending system will switch the object status to 'read-only' and then enter the replication message into a *replication queue* either in the sending system (for example, no connection) or in the receiving system (for example, master data issue) and alerts are created in AIF interfaces <code>DISTR\_IN</code> or <code>DISTR\_OUT</code> (both namespace /STTDI). The user responsible can be alerted via AIF capabilities and now can resolve the root cause and then restart the queue. For more information, see Queue Mechanism for Replication [page 164].

When replicating objects, also the related transactions, Lots and relevant events are being replicated.

Transactions and their relation to objects are replicated for visibility reasons but the responsibility is never handed over to another instance. When replicated a transaction will always have status visible (read only). The update of transactions is be rejected in case the status of the transaction is visible (read-only). This also affects creating or removing relations to such transactions.

Lots are replicated for visibility reasons but the responsibility is never handed over to another instance. When replicated a lot always will have the status visible (read only). In case an event is received for an LGTIN object that is visible only, the event is accepted but no updates are made to the LGTIN object. An according warning is logged.

As mentioned above only relevant events are replicated by default. For the objects to be replicated all related events are determined. These events will be split into two categories:

- Mandatory events which are required to represent a consistent history. This includes the initial
  commissioning event, potentially decommissioning events (objects events with action ADD or DELETE) as
  well as aggregation events that change the hierarchy (aggregation events with action ADD or DELETE).
- Optional events which may be replicated additionally to represent a complete history. This includes all remaining events.

By default only mandatory events will be replicated. A BAdl allows to add events from the group of optional events to the list of relevant events to be replicated.

For all events to be replicated all affected objects that are not included in the list of objects to be replicated are determined.

These additional objects will be replicated for information purposes in status visible (read only). This means that the control stays with the source system (no status change).

### **5.2.4 Deployment of Central and Local Instances**

This topic explains the deployment of Central and Local SAP Advanced Track and Trace for Pharmaceutical instances. Basically this deployment is project work. For detailed steps to configure the systems, please refer to the configuration guide and the *Administrator's Guide with Upgrade Information* at http://help.sap.com/attp.

The most important cornerstones of the deployment are as follows:

- Systems and logical system groups
- Connect Central Instance and Local Instances through RFC
- In General Customizing declare the central instance as Central Instance (**SYSTEM\_ROLE = C**) and the Local Instances as local ones (**SYSTEM ROLE = C**).
- Define master data objects System in central SAP Advanced Track and Trace for Pharmaceuticals
  - Central and local systems with logical system as system name, system type SAP Advanced Track and Trace for Pharmaceuticals Instance, communication type RFC and logical system as logical system
- Define the location assignment to local instances within customizing transaction /STTP/DISTR\_LANDSC Local System Landscape Configuration.
  - o If you are setting up a new local instance or if you are changing the plant location to system
    assignment within your landscape then please also make use of the options to replicate customizing
    and master data. In case there is affected transactional data which has to be replicated based on the
    new/changed setup then also choose the option to replicate transactional data.

- For more information, see the report documentation.
- The current setup can be displayed via transaction /STTP/CSYST\_LOC Location Assignment to Local Systems.
- Setup rules processing in all instances to replicate transaction data by creating rules with rule type BR DISTR DM
  - Do not forget to do this also in local instances as transaction data will be replicated back not only for regulatory reporting, but also when moving goods from one plant location to another, with different responsible SAP Advanced Track and Trace for Pharmaceuticals instances.
- Follow the following steps to ensure consistent master data in your landscape:
  - Either configure master data to be replicated online in general Customizing by activating parameters
     ONLINE\_BUP, ONLINE\_LOC, ONLINE\_PROD, ONLINE\_SNR\_NSP and ONLINE\_SYST (For more
     information, see the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the
     SAP Help Portal at http://help.sap.com/attp).
  - Or if online replication is not activated, run transaction /STTP/DISTR\_MD Replication of Master Data
    whenever you are changing or adding master data, to ensure that all needed master data is
    consistently available in all systems of your landscape.
- Whenever you change Customizing, run transaction /STTP/DISTR\_CUST Replication of Customizing to
  ensure that all systems in your landscape are configured consistently, to ensure a seamless functioning
  and data exchange.

### 5.2.5 Queue Mechanism for Replication

In a distributed SAP Advanced Track and Trace for Pharmaceuticals landscape with a central and one or more local systems, the online replication of master data is triggered when configured in general Customizing.

The transactional data is replicated via replication rules that have to be configured in the rules maintenance. The replication logic takes care to make all relevant transactional data known in the other relevant systems of the landscape. It further controls the status of the replicated objects so that they are only active in exactly one instance at a time, and visible in all other instances.

Unfortunately, reality proved that during this asynchronous processing there occurred errors which resulted in a failure of the replication (for example, because the system connection between local and central instance was temporarily not available, or because master data was not consistently synchronized). So, although replication is supposed to happen, it is stopped due to an error. The replication is cancelled and, for transactional data, results in incorrect object status values within the distributed system landscape.

To properly deal with such error cases, *replication queues* have been introduced. Whenever an error happens during data replication, the replication message is introduced either into the outbound replication queue of the sending system, or the inbound replication queue of the receiving system. Which queue the replication message is entered in depends on the error case. Errors which deal with connectivity or interface issues are typically stored in the outbound interface and errors which occur due to logical issues (for example, missing master data) are typically stored in the inbound interface.

During a replication process, replication messages are logged to AIF within own outbound/inbound interfaces. If the replication fails due to an error, in addition to entering the replication message to the replication queue, error messages are added to the respective AIF interface which can be used to notify a user about the replication error and a new entry in the replication queue. The user now can analyze and solve the issue that caused the replication failure and then restart or reprocess the queue.

The reprocessing can be triggered either from the AIF error monitor via action *Restart* or from the separate transaction *Replication Queue Monitor*. The *Replication Queue Monitor* can launched from AIF via a custom function or directly via transaction /STTP/DISTR\_QUEUE - *Replication Queue Monitor* or can be accessed from the SAP Menu, under Advanced Track Trace Repository Data Management Distributed Systems.

The existence of replication queues (outbound/inbound) for some target/source system will block future replication from/to the same system by creating new corresponding queues. During online replication of master data, such queues need to exist for the same objects as the ones subject to replication in order for the replication process to fail. During the online replication of transactional data, it is not checked whether specific objects stored in queues.

The Replication Queue Monitor allows restarting of a replication process for the stored data, as well as reverting by returning the control over an object instance (status *Active*) back to the source system.

In case of a replication failure, the complete RFC interface data is written as a serialized BLOB into queues for later reprocessing.

### Use

The queues are stored within own tables: /STTP/RFCQIN for inbound and /STTP/RFCQOUT for outbound.

Outbound Queues are written in the source system for cases where the sending of replication data fails due to some technical connection or interface issue. Typically, this would be a network failure or logon failure of the RFC connection.

If the data has been transferred correctly (technically received), the local messages as well as the messages from the receiver are logged to AIF and no queue is written. If the data has **not** been transferred correctly (technical error), an outbound queue is written, and the local messages as well as a specific outbound error message are written to AIF. If an outbound queue entry with the same target system exists, the replication data is **not** processed, but added as a new outbound queue entry.

Inbound Queues are written in the target system for cases where the receiving and posting of replication data fails due to some logical issue. Typically, this would be an inconsistency in related business objects like missing GTIN or status of the same.

If the data has been posted correctly (logical checks successful without errors), the local messages are logged to AIF and no queue is written. If the data has NOT been posted correctly (for example, logical checks not successful and such errors exist) none of the changes are committed to the DB, an inbound queue is written and the local messages as well as a specific inbound error message is written to AIF. If an inbound queue entry with the same source system exists (for master data contained objects are additionally checked), the data is NOT processed but added as a new inbound queue entry.

The *Replication Queue Monitor* can be called from the AIF error monitor transaction by calling AIF custom function for replication queue messages. In this case, the selection is executed based on the corresponding queue and the corresponding queue is displayed.

When calling the Replication Queue Monitor directly, you can filter based on the following:

- Queue direction (Inbound/Outbound)
- Source/Destination System (source for inbound /destination for outbound)

- Single Queue & Queue Internal ID (for selection and display of one specific queue)
- (Queue) Status the possible values are as follows:
  - o 1 In Process
  - o 2 Failed Logically
  - o 3 Failed Technically
  - 4 Blocked
  - o 5 Deleted
- Date + Time Range (update timestamp of queue)
- Include Suspended, Include Deleted

Choose Search to execute the selection.

The report lists the queues selected according to the selection criteria within an ALV grid (display only).

Multi-selection on the ALV grid is enabled to allow users to mark and execute actions on multiple selected queues.

If actions are executed against multiple queues, the action against the queue data is executed in the sequence of their creation timestamp.

In case of reprocessing, the AIF message needs to be updated accordingly: the stored message is overwritten.

Following actions are possible for selected queues in the ALV grid:

### List Objects:

Lists the replication objects for the selected queue within an ALV grid (display only) in a separate popup. For queues with Replication Object Type DISTR\_DM - Repository Objects, one can search for specific objects by filtering via the object code.

A list containing all replication objects corresponding to the selected queue can be exported (CSV format). This action can be only executed on a single queue.

- Restart: Dropdown menu entries Restart Selected and Restart All.
- **Restart Selected**: The payload data is read from the selected queues and the intended processing of the data is repeated (that is, RFC call or posting). In case of success, the queue is deleted from DB. In case of failure, the queue counter is updated and the status is set to the according failure status.

Restart can be executed if a queue is not suspended and has one of the following status values:

- 1 Failed Logically
- o 2 Failed Technically
- o 3 Blocked

The log entry in the queue is updated with the current messages for retrace purposes.

Restart all: All inbound/outbound queues for the selected source/destination system (when nothing is
entered, then all source/destination systems) are restarted (see Restart Selected). The processing logic
will detect any potential queue that has been added during processing, and also process such waiting
queues.

#### • Revert Selected:

This action can be only executed for queues with Object Type DISTR\_DM.

Upon replication start, the source system lost control over the replication objects (object status changes from 'active' to 'visible (read only)'. This change can be reverted here.

The payload data is read from the queue and a logic is triggered to revert the changes that were done in the source system due to the replication:

o Inbound queues: An RFC function on the source system is called to hand data back to the caller for reverting the changes in the source system that were done due to the replication call.

• Outbound queues: A logic is triggered to re-establish control of the replicated objects (native = control handover).

In case of success, the queue is deleted from DB. In case of failure the status is set to the relevant failure status.

Revert can be executed if a queue is not suspended and has one of the following status values:

- 1 Failed Logically
- o 2 Failed Technically
- o 3 Blocked

The log entry in the queue is updated with the current messages for retrace purposes.

• **Delete Selected:** The queue entry is marked as deleted, that is, status is set to 4 – *Deleted*. Deleted queues do not block any other replication call.

Delete can be executed for all queue statuses except 4 – Deleted.

No actions can be executed on queues marked as *Deleted*.

The log entry in the queue is not updated.

- **Suspend**: The queue is marked as non-blocking and subsequently does not block additional replication calls any more. This mechanism is only an emergency option in cases where additional data is urgently required for operations while the fix of errors in ongoing for the failed data. Suspend can be executed if a queue is not already suspended and has one of the following status values:
  - o 1 Failed Logically
  - o 2 Failed Technically
  - o 3 Blocked

No actions other than *Unsuspend* can be executed on suspended gueues.

The log entry in the queue is not updated.

- **Unsuspend**: The queue is marked as blocking again and subsequently blocks all queues with creation time later than the creation time of this particular queue. This mechanism is needed to be able to process the queues, which were marked as suspended. *Unsuspend* can be executed if a queue is suspended. The log entry in the queue is not updated.
- **Show in AIF**: Starts the AIF error monitor (TA /AIF/ERR) with the AIF message GUID that is stored within the queue. This action can only be executed on a single queue.

### **Locking Behavior**

To prevent parallel processing of queues in different tasks, on selecting queues within the *Replication Queue Monitor*, both database tables /STTP/RFCQIN and /STTP/RFCQOUT will be locked, and unlocked again upon leaving the *Replication Queue Monitor*. Consequently, restarting a queue from within AIF is not possible if the AIF error monitor (TA /AIF/ERR) is called from within the *Replication Queue Monitor*.

Restarting queues from within AIF will lock the corresponding (inbound/outbound) database table and unlock when processing ends.

### **Replication Queue Cleanup**

You can cleanup queues that are marked as deleted before x days via the transaction /STTP/
DISTR\_QCLEANUP - Replication Queue Cleanup, or via the SAP Menu, under Advanced Track & Trace Repository Data Management Distributed Systems.

### 6 SAP S/4HANA and SAP ECC Add-on for SAP Advanced Track and Trace for Pharmaceuticals

### Use

The SAP S/4 HANA and SAP ECC Add-On for SAP Advanced Track and Trace for Pharmaceuticals (ECC Add-on) handles the necessary ECC enhancements to ensure master data integration, transactional data integration and warehouse integration from SAP S/4HANA and SAP ECC to SAP Advanced Track and Trace for Pharmaceuticals. This add-on uses the standard enhancement capabilities of SAP S/4HANA and SAP ECC.

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals, then the master data objects and transactional objects are integrated to EWM as well to enable warehouse integration with the repository system in EWM. For more information, see EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals [page 194] and the configuration guide at http://help.sap.com/attp.

#### i Note

The features for the SAP S/4HANA Add-on are the same as for the ECC Add-on. If in sub-chapters or in other sections of the online help, a functionality contained in the ECC Add-on is mentioned, it can be assumed that the same functionality is also available within the add-on for SAP S/4HANA 1610 and 1709.

The support for SAP S/4HANA 1809 FPS01 can also be considered to have feature parity with the dedicated add-on installations mentioned above. Here, however, there is no need to install the add-on as its content is already part of the delivery of SAP S/4HANA and only needs to be turned on via a business function. The major change in this case however is that the storage of the GTIN has moved to the EAN field and therefore certain subsequent processes might be impacted. For more information, see SAP Note 2716224.

All functionality of the ECC Add-On for SAP Advanced Track and Trace for Pharmaceuticals can be accessed in the SAP menu, under Logistics Central Functions Advanced Track Trace.

#### **Features**

- Master Data maintenance and integration
  - o Customers and Vendors are integrated as Business Partners
  - o Plants and Storage locations are integrated as Locations
  - o Material master is enhanced and Materials are integrated as Trade Items
  - Trade item serialization attributes can be maintained in a separate transaction
- Transactional Data Integration
  - Production orders and process orders are integrated

- o Inbound deliveries, outbound deliveries and return deliveries are integrated
- Batch is enhanced and Batches are integrated
- Warehouse Integration with Warehouse Toolbox and SAP Advanced Track and Trace for Pharmaceuticals functions
  - Warehouse business functions (activities) which include validation and buffering for a series of typical warehouse activities.
  - o Compose and send EPCIS event message for warehouse activity
  - Warehouse comfort functions such as get contents, get hierarchy, serial number request
  - Warehouse test UI
  - RF demo implementation for inbound and outbound processing showcases potential usage of the toolbox
- eASN Handling
  - When shipping a delivery the serialized items and their hierarchies are queried from the repository system and an enriched ASN is composed that contains the items and the hierarchy
  - When receiving an eASN besides the creation of the inbound delivery also an EPCIS message to the repository system is composed and sent which contains all commissionings, aggregations and the shipping event.

### More Information

Master Data Maintenance and Integration [page 170]

Transactional Data Integration [page 179]

Warehouse Integration [page 184]

Enriched Advanced Shipping Notification (eASN) [page 191]

### 6.1 Master Data Maintenance and Integration

### Use

SAP Advanced Track and Trace for Pharmaceuticals needs master data in order to identify, interpret, and process transactional data. Typically, master data is integrated from an external system to SAP Advanced Track and Trace for Pharmaceuticals . In many cases this external system is a SAP ECC system. However, SAP Advanced Track and Trace for Pharmaceuticals offers open APIs which you can use to also connect non-SAP systems. Besides this you can also maintain master data locally in the repository system without integration from any external system.

In general, the integration from multiple logical systems is also supported for maser data objects. Therefore, the Logical System Group parameter is stored at the respective master data entity. The external ID of a master data entity is only unique together with the logical system group.

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals, then the master data objects are integrated to EWM as well to enable warehouse integration with the repository system

in EWM. For more information, see EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals [page 194] and the configuration guide at http://help.sap.com/attp.

### More Information

- Integration of Customers and Vendor as Business Partners [page 171]
- Integration of Plants and Storage Locations as Locations [page 172]
- Enhancement of Material Maintenance [page 173]

## **6.1.1 Integration of Customers and Vendor as Business Partners**

### Use

Integration from SAP ECC to the repository system is done through a batch report.

### Integration

ECC vendors and customers are integrated to the repository system as Business Partners or Business Partner Roles. If a vendor and a customer share the same Global Location Number (GLN) in ECC, they would reflect in the repository system as one Business Partner with two roles – customer and vendor. Hence, only one Business Partner is created with two roles. If a customer or a vendor is not assigned with GLN or is assigned with different GLNs, they are integrated as independent Business Partners with the customer role and vendor role respectively.

### i Note

You can merge the role of two business partners using the Merge Role feature in the Business Partner entity in the Data Cockpit.

Customers and vendors are not extended in ECC and are integrated in their current state. The integration is always a full update which means that for all selected business partners in ERP always all attributes are integrated and overwritten in the repository system.

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals then the relevant business partners are also integrated to EWM via standard CIF. All relevant attributes are already integrated today (esp. the GLN assigned to the business partner).

### • Integration Report for Business Partners

In the ECC system, you can access the integration report by navigating to SPRO SAP Implementation

Guide Advanced Track and Trace Repository Integration Business Partner Integration.

Alternatively, you can use the transaction /STTPEC/INT\_BUP to access the report integration screen. The screen provides two report selection parameters:

- Vendor Selection
  - Business partner type for vendor selection
  - Account number of Vendor or Creditor
- Customer Selection
  - Business partner type for customer selection
  - o Customer Number

To integrate only business partners which have GLN assigned select the appropriate checkbox on the screen

To activate the business partners directly with the integration select the checkbox *Activate Business Partner* 

To enable vendor and customer selection based on the Business Partner Type, you must perform a customizing activity to map the vendor account group and customer account group to the Business Partner Type. For data selection, the vendor account groups and customer account groups are determined and used as criteria for data selection. For more information about the Customizing activity, refer to the Configuration guide.

## **6.1.2 Integration of Plants and Storage Locations as Locations**

### Use

You can integrate the Location entity in the repository system from SAP ECC through a batch report.

### Integration

Plants and Storage Locations in the ECC system are integrated to the repository system as Locations of Types Plant and Storage Location. Storage Locations are created as child locations of the Plant Locations which are the parent locations.

Plants and storage locations are not extended in ECC and are integrated in their current state. The integration is always a full update, which means that for all the selected Plants and Storage Locations in the ECC system always all attributes are integrated and overwritten in the repository system.

- Integration Report for Plant and Storage Locations
  - In the ECC system, you can access the integration report by navigating to Advanced Track and Trace
     Repository Integration Plant & Storage Loc. Integration Alternatively, you can use the transaction /STTPEC/INT\_LOC to access the report integration interface. The screen provides two report selection parameters, Plants and Storage Locations.

To integrate only plants which have GLN assigned, select the appropriate checkbox on the screen. To activate the Locations directly with the integration, select the checkbox *Activate Location*.

Whenever a plant is integrated to the repository system, during data collection, the ECC system checks if a GLN is assigned to the plant and only then it transfers the GLN together with the plant to the repository system.

### i Note

Assignment of GLN to plant is done within transaction EANGLN

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals, then the plants are already integrated as locations via CIF today. For more information, see EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals [page 194].

### 6.1.3 Enhancement of Material Maintenance

### Use

This topic explains the enhancement of Material Maintenance and Material Integration as Trade Items. As part of Material Master Integration, you need to create the Material Master data in the ECC system. This add-on provides enhancements to the Material Master Maintenance and enables the integration of the material masters as trade items.

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals then the material is also integrated to EWM. For more information, see EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals [page 194].

#### **Features**

### Material Maintenance in ECC

This Add on extends the existing material maintenance in ECC with serialization attributes needed by SAP Advanced Track and Trace for Pharmaceuticals. Most of the necessary trade item attributes can be maintained in ECC and integrated to SAP Advanced Track and Trace for Pharmaceuticals. The material master database tables and maintenance UIs have been extended for this purpose.

The primary trade item identifier in SAP Advanced Track and Trace for Pharmaceuticals is the Global Trade Identification Number (GTIN). Within the ECC material maintenance the GTIN is assigned on the tab *Units of Measure* ( Material Maintenance Additional Data Units of Measure ). On this tab the alternative units of measure for the material are defined and the packaging hierarchy is defined. As a trade item reflects a particular unit of measure in a packaging hierarchy the GTIN is assigned to the alternative UoM. In case the serialization indicator is set then this GTIN is integrated as a trade item to SAP Advanced Track and Trace for Pharmaceuticals. The material reference is also integrated but just as additional context information to enable for example, search of trade items by material number. It is possible to assign different GTINs to different alternative UoMs of a material and integrate all of them. In this case in SAP Advanced Track and Trace for Pharmaceuticals there will be different trade items with the same material reference. Under certain conditions the same GTIN can be assigned to different materials. After integration there will be one trade item with several trade item variants (each variant representing one material assignment).

### i Note

Starting with SAP S/4HANA 1809 FPS01, the maintenance of the GTIN has been moved to *Additional EANs* under *Material Maintenance Additional Data*. For more information, see SAP Note 2716224.

To enable seamless integration with SAP Advanced Track and Trace for Pharmaceuticals, the add-on provides the following enhancements:

- Material Master Database tables MARA, MARC, and MARM have been extended with serialization attributes
- Configurable sub-screens that you can activate in order to display the trade item serialization attributes in the classic material master UIs
- A new transaction to display and maintain trade item serialization attributes for a material
- Mass Maintenance application or transaction MM17 to enable mass maintenance of the trade item serialization attributes

#### Material Master UI

The following are the material master and UI enhancements accessible via classic material master UIs (transactions MM01, MM02 and MM03):

- Advanced Track and Trace Material Header Settings: These attributes are provided under the *Basic Data* tab view and are valid across all plants.
  - Here you can select the Serialization Type to define if a material is relevant for tracking and tracing. Apart from the Serialization Type values that exist in both ECC and the repository system, an additional entry is available in the ECC. This is the type not serialized. This is the default value for all new materials and denotes that the material is not relevant for tracking and tracing. All the other serialization types denote that the material is relevant for the repository system. However, the actual integration is triggered when you select the Serialization indicator. For more information, see section on Units of Measure below.
  - You can assign the profile relevant country which is needed in SAP Advanced Track and Trace for Pharmaceuticals to determine the serialization profile. Maintain this parameter if you want to use option Assign Create Range Definition during integration (for more information see section on Trade Item Integration).

### → Tip

It is possible to maintain additional country assignments in transaction <code>/STTPEC/TRD\_ITM\_SER-Maintain trade item serialization attributes</code>

- You can assign the *Product Category* which is needed in SAP Advanced Track and Trace for Pharmaceuticals to auto-determine the range definition for particular serialization profiles. Maintain this parameter in case you want to use option *Assign Create Range Definition* during integration. and if you are using serialization profiles that require the product category.
- The check box *Synchronization Active* indicates if the material is already integrated to the repository system.
- The atttribute Last Synchronized displays the time and date of the last synchronization occurred between the ECC system and the repository system. After the first integration to the repository system, you cannot switch the Serialization Type to non-serialized anymore.
- Advanced Track and Trace Material Plant Settings: The Serialized From date attribute under the Work Scheduling tab view and is valid for one plant.

This attribute denotes a date for every plant and this date determines if a new batch for this material
has to be treated as serialized or not. For more details see Batch Enhancements and Integration [page
182].

### i Note

Always give a future date (today + 1 day) in the Serialized from date. This date can only be changed as long as it lies in the future. As soon as the date reaches the current date the field changes to read only and cannot be changed anymore.

- Units of Measure: The add-on provides extensions in Additional Data Units of Measure tab view. Here you can maintain the following serialization relevant attributes:
  - OGTIN: The Global Trade Identification Number (GTIN) is the primary identifier of a trade item in SAP Advanced Track and Trace for Pharmaceuticals. The GTIN is a mandatory attribute if the UoM has to be integrated as a trade item (serialization indicator = true). After integration the GTIN cannot be changed or deleted anymore from the alternative UoM within this UI.

    With SAP S/4HANA 1809 FPS01 or higher, you must use the fields *EAN/UPC* and *EAN cat.* in

    Additional Data Additional EANs tab view to provide the GTIN, as the GTIN field in the MARM structure has been removed. For SAP Advanced Track and Trace for Pharmaceuticals to consider the value from these fields in the MEAN table as GTIN, the corresponding EAN category needs to be set in General Customizing. To do this, maintain parameter /STTPEC/ MD EANCAT 4 GTIN14 in the transaction /STTPEC/CUSTGEN.
    - o In certain cases, one GTIN can be assigned to different materials. However, this is possible only if all materials have exactly the same serialization relevant attributes.
    - O Deletion of GTIN: Under certain conditions a GTIN can be deleted from the alternative UoM. Within the repository system the transaction /STTP/DEL\_TR\_ITM\_VAR Delete Trade Item Variant can handle the deletion of a trade item variant both in the repository system as well as in all connected SAP ECC systems. Only via this report a consistent cross-system deletion of the trade item variant and the assignment of the GTIN to the UoM of a material can be ensured. In exceptional cases the cross system deletion may not succeed and the user may decide to just do a local deletion of the variant in the repository system and do a separate cleanup in the connected ECC systems afterwards. Therefore (and only for this purpose) there is also a local deletion function in ECC: transaction /STTPEC/DEL\_GTIN Locally Delete GTIN from Material.

### 

Use this transaction with extreme care. It just deletes the serialization attributes locally in ECC. After execution you can assign a new GTIN to a UoM that has been integrated to the repository system before, but if the deletion was not done in the repository system before, then the new GTIN cannot be integrated as the material still is assigned to another GTIN.

- Serial Number Management Type: Indicates that this trade item will be serial number managed in SAP Advanced Track and Trace for Pharmaceuticals. The attribute can have the following values:
  - Initial: Not defined/ not serial number managed. In this case, it is not defined whether serial
    number management shall be done for this trade item. The trade item can be activated with or
    without a serial number range definition assigned.
  - X: Internal serial number management. In this case, the trade item is subject to internal serial
    number management and a range definition with origin *Internal* will be created. *Internal* indicates
    that the serial numbers and ranges are owned and generated within this system. Activation of the
    trade item is only possible if a range definition with origin *internal* is assigned to the trade item.

- E: External serial number management. In this case the trade item is subject to external serial number management, and a range definition with origin External will be created.
   Activation of the trade item is only possible if a range definition with origin External is assigned to the trade item. You need to reference a customer that represents the source of the serial numbers to allow automated creation of range definitions..
- Business Partner (Customer) to provide Serial Number: In case of serial number management type external serial number management, your company, for example, acts as contract manufacturer (CMO) for a Marketing Authorization holder (MAH). In this scenario, you do not generate the serial numbers within your system but you request the numbers from the MAH via serial number request. This attribute is to specify the business partner (customer) which is your MAH and which provides the serial numbers to you (as a prerequisite this business partner must have a notification system assigned and this system must be connected to your MAH via web service or RFC. Also, an appropriate serial number request type must be defined and an external system name must be specified for the system).
- National Code and Type: Add national code and type as an additional alternative identifier of a trade item in the country defined as profile relevant country. The combination of national code and type must be unique. Duplicates are not allowed.

→ Tip

It is possible to maintain additional national codes for every additional country assignment in transaction /STTPEC/TRD ITM SER - Maintain trade item serialization attributes.

- **Registration Code**: Here you can assign a registration code issued by a particular country that can be used as an additional alternative identifier of the trade item.
- Serialization Indicator: The ECC system integrates only those UoMs for which the Serialization Indicator check box is selected.
- UoM Synchronization Active: This flag indicates that the particular UoM has been integrated as trade item to the repository system. In addition, this field handles the edit ability of the following fields: in case a UoM is integrated (flag = true) then the following fields cannot be changed anymore in ECC:
   GTIN, Serial Number Management Type, Serialization Indicator.

#### New Transaction to Display And Maintain Trade Item Serialization Attributes For a Material

Transaction / STTPEC/TRD\_ITM\_SER - Maintain trade item serialization attributes allows you to display and maintain trade item serialization attributes. Besides that, integration to SAP Advanced Track and Trace for Pharmaceuticals can be triggered for selected trade items.

The transaction consists of a search pane, a result list and a details pane with tabs that display the different serialization attributes:

### Search pane

 You can search for materials by different search attributes such as material ID, GTIN, national code and certain status values.

### Result list

- The result list displays one line per alternative UoM of a material. So you have both the material and also the alternative UoM in the context. Both the tabs in the details pane as well as the actions of the result list either refer to the material as a whole (MARA) or to the alternative UoM only (MARM)
- Here, a mixture of standard MARA and MARM attributes is displayed plus the relevant serialization attributes
- Display GTIN Usage: When triggering this function, a popup is launched that displays the usage of the GTIN. The same GTIN can be assigned to different materials as long as certain conditions apply likefor

example, same base UoM, same alternative UoM, same serialization attributes. In case you assign the GTIN to multiple materials then it may be necessary to synchronize the serialization attributes across all the materials that use the same GTIN in order to enable consistent integration with SAP Advanced Track and Trace for Pharmaceuticals. So within this popup, all materials are shown that use the same GTIN, and inconsistencies are highlighted. In case of inconsistencies, the user can trigger different actions to bring the system to a consistent state. When saving changes of a material within this transaction then this consistency check is also executed and the popup is launched actively in case inconsistencies are detected. Before saving the material the inconsistencies must be solved.

- Action *Material*: Navigates to the material. Navigation to MM02 when in edit mode and to MM03 when in change mode.
- Action Sync EAN/GTIN: Enables synchronization of GTIN with EAN/UPC or vice versa for the selected alternative UoM only.
- Locking Behavior: When in edit mode, the currently selected material is locked. When selecting
  another material the changes need to be saved before. So only one material is locked at the time.
   Exceptions: the action *Integrate Trade Items* needs to lock all materials selected and the popup *Display*GTIN Usage can trigger actions that also require locking of multiple materials.
- Action Integrate Trade Items: Triggers integration of the selected material to the repository system

#### • Tab Details

• On this tab you can manage the serialization attributes of the material header (MARA). The behavior is the same as described in section **Material Master UI**.

#### • Tab Plant Data

On this tab you can display plant assignments for the selected material and you can maintain the
attribute Serialized From Date for existing plant assignments (MARC). The behavior is the same as
described in section Material Master UI.

#### • Tab Alt UoM Details

on this tab you can display details for the alternative UoM and maintain all serialization attributes on this level. The behavior is the same as described in section **Material Master UI**.

### • Tab UoM Countries

On this tab you can maintain additional country assignments to the trade item and in addition you can
assign country- specific national codes, national code types and registration code. The profile relevant
country is also displayed here for information but it can neither be removed nor changed. The profile
relevant country can be changed on tab **Details** and the national code for the profile relevant country
can be changed on tab *Alt UoM details*

### i Note

Important: This tab is stored in a special database table that refers to the GTIN and not to the material. This means that the data maintained on this tab is shared across all materials that use the same GTIN. Therefore data can be maintained only as soon as a GTIN is assigned to the alternative UoM.

#### • **Tab** Additional Attributes

On This tab, you can add the property name or property value attributes to the trade item. Property names can be defined in Customizing of the SAP Advanced Track & Trace for Pharmaceuticals System (not in the ECC system) under SAP Advanced Track and Trace for Pharmaceuticals System Parameters Product Property Names.

SAP delivers a set of properties required for regulatory reporting for certain countries. You need to maintain these properties for trade items if regulatory reporting for these countries is considered.

By using Assign Country-Specific Attributes, you can assign all required country attributes at once. Based on the assigned countries, the relevant attributes are determined and added. For Europe, the attributes are only added if at least one country is assigned to the trade item that is relevant for reporting to the European Hub.

### i Note

Country relevance for European Hub is maintained in Customizing.

By using *Check Country Reporting Attributes*, you can check whether all attributes have been maintained correctly to ensure a successful regulatory reporting

### i Note

In General Customizing, you can define whether this check is executed on the activation of the trade item and whether check errors are only logged or whether they shall block the activation. For more information, see the chapter *General Customizing (ATTP)* for parameter CHECK\_RR\_CNTRY\_MSTR in the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>.

For more information, see Outbound Processing [page 89] for Regulatory Reporting and Supply Chain Reporting Framework.

### i Note

There is no synchronization of additional attributes from the SAP Advanced Track & Trace for Pharmaceuticals repository instance to SAP ECC or SAP S/4HANA. If Additional Attributes are added on the SAP ECC side, they will overwrite the existing attributes on the repository instance.

#### **Trade Item Integration**

Materials can be integrated either online or through batch report.

Unlike the *Business Partner* and *Location* where all the selected objects are always transferred for integration, the material integration uses only the changed materials for integration. Therefore, while saving changes to a material, the system checks for differences in the attributes relevant for Serialization. If the system detects differences, the check box *Changed Since Integration* is set. Furthermore, you can use the Customizing activity /STTPEC/V\_PMDCF - *Maintain Material Fields* to define additional fields of the material master that triggers the integration. For more information, see the configuration guide at http://help.sap.com/attp.

Online Integration of Material to Repository System During Save
In case online integration for materials is activated, the system automatically triggers this type of
integration if a material is changed and the integration relevance for the material is determined. However,
this type of integration is only applicable for material changes.

### i Note

The very first integration to SAP Advanced Track and Trace for Pharmaceuticals must always be triggered through the report. You can configure online integration using the General Customizing. Refer to the Configuration guide for more details.

• Integration from SAP ECC through Report
You can use the batch report (transaction / STTPEC/INT\_MAT - Material Master Integration) which allows
initial and delta integration of new or changed materials. Delta Update ensures the integration of only those

materials for which the changed since integration is selected. *Full Update* ensures the integration of all materials which are relevant for serialization. Optionally you can trigger activation of trade items and assignment / creation of serial number entities (range definition and range) at integration. By maintaining all serialization attributes in the material master maintenance and by setting these two flags you may integrate the trade item, create and activate serial number entities and activate the trade item. As a result you may directly start requesting serial numbers and commission serialized items without any further manual interaction in the repository system. As a prerequisite you have to define a range automation profile and assign it to the serialization profile in the repository system. If you are dealing with externally managed serial number range definitions (serial number management type *E*), then, in addition, you need to ensure that *Business Partner to provide Serial Number* is maintained, and that in the repository system the notification system is assigned to this business partner, and for this system all relevant data to trigger a serial number request is maintained. For more information, see Serialization Profile [page 34]. For more information, see the report documentation.

### 6.2 Transactional Data Integration

### Use

The transactional data integration handles the integration of business transaction documents such as production order, purchase order, process order, inbound delivery, outbound delivery and return delivery and furthermore it handles the integration of the batch from SAP ECC to SAP Advanced Track and Trace for Pharmaceuticals.

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals then the relevant inbound and outbound deliveries are also integrated to EWM and the delivery integration has been enhanced as part of the Add-On with additional attributes needed. No additional configuration is necessary. For more information see EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals [page 194].

### **More Information**

Integration of Transaction Documents [page 180]

Batch Enhancements and Integration [page 182]

# 6.2.1 Integration of Production Orders, Process Orders, Purchase Order, Inbound Deliveries, Outbound Deliveries and Return Deliveries

#### Use

The ECC Add-on for SAP Advanced Track and Trace for Pharmaceuticals offers the option to integrate business transaction documents such as production order, purchase order, process order, inbound delivery, outbound delivery and return delivery.

The business transaction document will be created with items and the processing status of the business transaction document is integrated as well and reflected as business transaction item status and business transaction summary status. Besides this the following item attributes are also integrated:

- Planned quantity: Total quantity of an item planned for execution.
- Confirmed quantity: Actual item quantity which was posted as goods movement.
- Batch / Lot number: Batch / Lot number assigned to a business transaction document item.

In case of split items both the parent item as well as the split items are integrated. The parent only carries a planned quantity as long as the total planned quantity is not fully assigned to the split items (Remark: Item split can happen for outbound deliveries for example, in case different batches executed for one item).

### Integration

### General Behavior

- Within ECC Add-On
  - It can be configured in general customizing whether inbound deliveries, outbound deliveries, (return deliveries are special outbound deliveries), production orders, process orders and purchase orders shall be integrated (in general or per plant)
  - Furthermore it can be configured whether a business transaction document shall be integrated immediately (online) or only through integration report
  - The relevant business transaction document items and sub items are integrated as well.
  - Integration is triggered at creation/release of transaction and in case relevant business transaction data is changed.

### Example

- Deletion of transaction
- Deletion/addition of item
- o Update item: e.g. because of change of planned quantity or assignment of batch
- Split of item
- Update confirmed item quantity at post goods movements

For more information, see the configuration guide at http://help.sap.com/attp.

- Within SAP Advanced Track and Trace for Pharmaceuticals:
  - When a business transaction first is integrated the document status is set to initially integrated

- The business transaction type reflects the GS1 core business vocabulary (prodorder for production order, recadv for inbound delivery and desadv for outbound delivery and rma for a return delivery and po for purchase order)
- The document type and document number reflect the document type and number known to ECC
- The transaction summary status reflects the summary of all item status values.
- O Business Transaction items contain the following information:
  - o Item number
  - o GTIN
  - o Item status
  - Planned quantity and confirmed quantity
  - Batch/lot

#### **Specifics for Delivery Integration**

- Deliveries are integrated after creation
- By using parameter TRN\_GM\_SEND Send Goods Movement Event to SAP Advanced Track and Trace for Pharmaceuticals, it can be configured in general customizing whether action "post goods movement" inbound delivery, outbound delivery or return delivery shall compose and send a receiving or shipping event for all objects that are currently related to the transaction.
  - Post Goods Receipt for Inbound Delivery
    - o Query all objects related to transaction from SAP Advanced Track and Trace for Pharmaceuticals
    - o Compose Object Event with Action Observe and Business Step Receiving
      - o EPC list as determined
      - Disposition: active
      - o Read point/Business location: determined from plant (EANGLN)
      - o Source/Destination: determined from inbound delivery
  - Post Goods Issue for Outbound Delivery
    - o Query all objects related to transaction from SAP Advanced Track and Trace for Pharmaceuticals
    - o Compose Object Event with Action Observe and Business Step Shipping
      - EPC list as determined
      - Disposition: in\_transit
      - Read point: determined from plant (EANGLN)
      - o Business location: empty
      - o Source or Destination: determined from outbound delivery
  - o Post Goods Receipt for Return Delivery
    - o Query all objects related to transaction from SAP Advanced Track and Trace for Pharmaceuticals
    - o Compose Object Event with Action Observe and Business Step Receiving
      - o EPC list as determined
      - Disposition: active
      - Read point/Business location: determined from plant (EANGLN)
      - Source/Destination: determined from return delivery
- When reverting post goods issue of outbound delivery, post goods receipt of return delivery or post goods receipt of inbound delivery via transaction VL09 Cancel Goods Issue for Delivery Note, the solution composes and sends an opposite event message. To revert a shipping event, a receiving event is composed and sent, and vice versa.
- For more information, see the configuration guide at http://help.sap.com/attp.

#### **Specifics Production or Process Order Integration**

- The output material is integrated as item 1
- Integration is triggered only when releasing order

## 6.2.2 Batch Enhancements and Integration

#### Use

This topic is about Batch enhancements and integration from SAP ECC to SAP Advanced Track and Trace for Pharmaceuticals and to EWM.

#### **Batch Enhancements**

The batch data base tables in ECC are enhanced with following attributes

- Serialization type: denotes whether the batch is not serialized, lot managed, or serialized
- Synchronization time stamp: time when the last synchronization of the batch happened
- Synchronization active flag: if true the batch has been successfully integrated to the repository system

These additional attributes are not visible in the standard batch transactions in ECC but you can visualize them through report /STTPEC/INT BATCH Batches Integration.

The serialization type of the batch is determined during creation of the batch and it is determined in two different ways:

- In case the batch has a manufacturing date assigned then the serialization type of the batch is determined based on the manufacturing date and the serialized from date. If the manufacturing date is the same or later than the serialized from date the serialization type of the material header is copied to the batch. If not the serialization type of the batch is set to not serialized.
- In case the batch has no manufacturing date assigned, then the serialization type of the batch is determined based on the creation date of the batch and the serialized from date. If the creation date is the same or later than the serialized from date the serialization type of the material header is copied to the batch. If not the serialization type of the batch is set to not serialized.
- This logic is encapsulated within a BAdl and can be changed if wished. Please refer to the configuration guide for further details.

The attributes synchronization time stamp and synchronization active flag are set after successful integration of the batch.

#### Batch Integration from SAP ECC to SAP Advanced Track and Trace for Pharmaceuticals

The Batch can be integrated as Lot (LGTIN) from SAP ECC to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Prerequisites**

- Customizing
  - In the General Customizing in ECC it has to be defined whether lot level batches or serialized batches shall be integrated to SAP Advanced Track and Trace for Pharmaceuticals. If neither of the two is active, then it is not possible to integrate batches

- ECC Material master:
  - Tab Basic Data 1 (MARA): Serialization Type must be other than not serialized
  - Tab Work Scheduling (MARC): Serialized From must be maintained
  - o ECC material must be integrated to SAP Advanced Track and Trace for Pharmaceuticals
- Batch master
  - o Batch master must be created for plant

The Batch integration is triggered online after a successful creation of a plant batch.

- An object event with action *ADD* is composed for the LGTIN and sent to SAP Advanced Track and Trace for Pharmaceuticals via the OData interface.
  - The disposition of the event is determined based on the batch status as following
    - Batch status restricted results in event disposition non sellable other
    - Batch status *non-restricted* results in event disposition event disposition active
  - Batch attributes like expiry date and manufacturing date are included within the SAP extensions (if data is set in ERP).
  - The quantity list of the event just carries the LGTIN in EPC URI format and no quantity. This indicates that the message addresses the complete Lot.

The batch integration is triggered online after a successful change of the plant batch

- An object event with action *OBSERVE* is composed for the LGTIN and sent to SAP Advanced Track and Trace for Pharmaceuticals via the OData interface.
  - The quantity list of the event just carries the LGTIN in EPC URI format and no quantity. This indicates that the message addresses the complete Lot.
  - The disposition depends on the status of the batch (see above).
  - If maintained, batch attributes like expiry date and manufacturing date are included within the SAP extensions. Such attributes can only be updated in the repository system as long as the batch is restricted (disposition in repository system = non sellable other). In case the batch staus is unrestricted (disposition in repository system = active), then change within the repository system is not possible, and these attributes will be neglected during event processing and a warning is logged. For further details, see Lot [page 62].

#### Integration of Produced Quantities for Batch

Produced quantities for a batch can be integrated from SAP ECC to SAP Advanced Track and Trace for Pharmaceuticals in order to allow comparisons with the serialized trade items (reconciliation of data).

#### Prerequisites

- Material and batch must be integrated to SAP Advanced Track and trace for Pharmaceuticals
- Production order
  - o Batch reference must be maintained at production order

Whenever a goods receipt is posted in transaction MIGO with reference to the production order and the batch then an object event with Action *ADD* is composed for the LGTIN and sent to SAP Advanced Track and Trace for Pharmaceuticals through the OData interface.

- This time the quantity list carries the LGTIN and the quantity that has been confirmed in MIGO for the batch. (Remark: as soon as the quantity is defined, this means that the event message does not deal with the batch as a whole, but just with a partial quantity of the batch. As a consequence the event processing will ignore changes that refer to the lot as a whole. See below.)
- Furthermore the event carries a transaction reference to the production order.

- The disposition depends on the status of the batch (restricted vs non-restricted).
- Batch attributes like expiry date and manufacturing date are included within the SAP extensions if defined. However, in case of an event that carries a batch quantity, these attributes are only set in the repository system if they are initial and not defined yet. Changing the manufacturing or expiry date of an LGTIN is only possible in case the quantity list carries no quantity and with this addressing a partial quantity of the batch.

#### **Batch Integration Report**

In case the necessary prerequisites are not met then the online batch integration will fail. However the batch still is marked as relevant for integration and the transaction /STTPEC/INT\_BATCH Batches Integration enables you to select these batches and integrate them as soon as the prerequisites are met. Besides this you can also visualize already integrated batches. In addition to the standard batch attributes the report also visualizes the batch extension attributes such as serialization type, synchronization time stamp and synchronization active flag. For more information please refer to the documentation within the transaction.

#### Batch Integration from SAP ECC to EWM

Ifyou are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals, then you have to ensure that certain batch attributes needed for serialization are also replicated as batch characteristics in ECC as the standard way to handle batch attributes in EWM is via characteristics. For more information please see EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals [page 194].

## 6.3 Warehouse Integration

#### Use

In a typical business scenario, whenever a serialized item is moved into or out of a warehouse, one has to update not only the stock management, but also the serialization repository accordingly. In case those two worlds are updated separately this results in a high risk of data inconsistency.

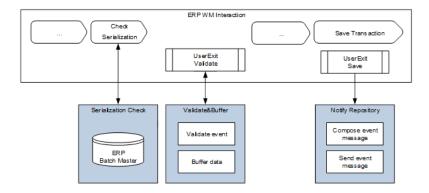
The Warehouse integration allows you to integrate warehouse stock with the serialization repository and with this to ensure cross data consistency.

SAP Advanced Track and Trace for Pharmaceuticals offers open interfaces for integration of any warehouse and an even more comfortable warehouse toolbox for SAP EWM as part of the ECC Add-On.

Typically warehouse environments are highly modified applications beyond the SAP standard. Because of this the warehouse integration follows a toolbox approach with numerous backend functions that can be used as needed and integrated with custom warehouse processes and screen sequences.

The fundamental paradigm of the warehouse integration is that the warehouse process is the leading process and the repository system is invoked if necessary. Only with this approach it can be assured that both serialized items and non-serialized items can be handled together.

The following picture depicts the general principle how the toolbox is used to create an end to end integrated business flow:



#### **Structure**

- Serialization check (synchronous)
  - Determine if the materials to be moved are serialized or not based on the serialization type available for every batch. For any kind of warehouse processes the following high level steps need to be followed:
  - If the materials are not serialized, the SAP Advanced Track and Trace for Pharmaceutical system must not be invoked into the warehouse scanning flow.
  - If the materials are serialized, the repository system must be invoked into the warehouse scanning flow which basically means that the serialized items must be scanned.
- Validate activity and buffer (synchronous)
  - After every scan, a fast online validation for the respective serialized item is done for the respective warehouse activity. The verification is done to the SAP Advanced track and Trace for Pharmaceutical system which provides immediate feedback informing if this warehouse activity is allowed or not.
  - If the activity is allowed for the item, it is buffered in the context of the activity waiting for the triggering of the surrounding warehouse processes.
  - o If the warehouse process is cancelled, the buffer is released.

- Compose and send event (asynchronous)
  - If the warehouse process is saved, the toolbox reads the buffered data and composes the respective EPCIS event message (object event, aggregation event, transaction event) and sends the message to the repository system.

#### **Activities**

The warehouse toolbox supports the following warehouse activities or business functions:

- Inbound processing
  - Receive container
  - o Receive document
  - Put away
- Internal processing
  - Pack (aggregate)
  - Unpack (dis-aggregate)
  - Commission objects
  - o De-commission objects
  - o Create or remove document relation
  - Count Hierarchy
  - o Inspect item
  - Inspect Hierarchy
  - Aggregation Accuracy
  - o Sample
  - o Pack or unpack
  - o LGTIN
  - Identify parent
  - Request Object Control
- Outbound processing
  - Pick
  - Pick to pallet
  - Load container
  - Ship container
  - Ship document

For any kind of warehouse processes the following high levelThe toolbox uses open interfaces of SAP Advanced Track and Trace for Pharmaceuticals modeled as OData Services for validation and also for event receiving (Alternatively, the toolbox can be also connected via Remote Function Modules. To find out how to switch between OData and RFC, see chapters *Communication options between ECC warehouse toolbox and ATTP* and *Communication options between EWM warehouse toolbox and ATTP* in the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>). These interfaces can be used to connect non-SAP warehouses. In this case, a functionality similar to the toolbox needs to be developed within the non-sap warehouse to feed the interfaces.

Besides the warehouse toolbox backend functions a test UI is available which can be used to test the functionality of the warehouse toolbox. The test UI can be accessed through transaction /STTPEC/WHS\_TOOLBOX Warehouse Activity Test Client. Although it looks like a highly integrated transaction the ECC objects are mocked away in this test UI so it can be used irrespective of whether the objects exist in ECC or not.

In addition to the test UI, an RF demo implementation is delivered that demoes the usage of the toolbox and shows an exemplary implementation of orchestrated processes across WM and SAP Advanced Track and Trace for Pharmaceuticals. The following example processes are supported in the demo:

- Inbound processing
  - Unload Inbound Delivery
  - Putaway Transfer order
- Outbound processing
  - o Pick Transfer order
  - o Pack Delivery Pallet
  - Ship Delivery Pallets

#### More Information

Warehouse Toolbox Activities [page 187]

#### 6.3.1 Warehouse Toolbox Activities

- Inbound Processing Business Functions [page 187]
- Internal Processing Business Functions [page 188]
- Outbound Processing Business Functions [page 190]

## **6.3.1.1** Inbound Processing Business Functions

#### Use

Given below are the Inbound Processing business functions:

#### **Process**

#### **Receive Container**

This business function validates whether a particular SSCC or SGTIN can be received. In case of an SSCC it
can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided. Furthermore it
can be checked whether the scanned items belong to a business transaction or alternatively the relation to
a business transaction can be created. If all validations succeed the data is buffered. Upon save a
corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Receive Document**

• The business function determines all serialized items that are related to a document and validates whether the items can be received. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Put Away**

• This business function validates whether a particular SSCC or SGTIN can be put away. In case of an SSCC it can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

## **6.3.1.2** Internal Processing Business Functions

#### Use

Given below are the internal processing business functions:

#### **Process**

#### Pack (aggregate)

• This business function validates whether a child item can be packed into a parent item. In case the parent item is an SSCC it can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided. Furthermore it can be checked whether the scanned items belong to a business transaction or alternatively the relation to a business transaction can be created. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### Unpack (dis-aggregate)

This business function validates whether a child item can be unpacked into a parent item. In case the
parent item is an SSCC it can be checked whether the SSCC corresponds to an HU with same ID if the HU
is provided. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is
composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Commission Objects**

• This business function validates whether a particular SSCC, SGTIN or LGTIN can be commissioned. In case of an SSCC it can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided. In case the object id is not provided a serial number request is issued to the repository system and the object is commissioned with this serial number. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **De-commission Objects**

• This business function validates whether a particular SSCC, SGTIN or LGTIN can be de-commissioned. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Create or Remove Document Relation**

• This business function validates whether a transaction relation can be created / removed for the SSCC or SGTIN. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Count Hierarchy**

• This business function is a utility function that does not send an event message but it is a supporting function that can be used in counting processes e.g. during inventory count. The business background is that in case of inventory count the warehouse worker will have to count all unopened packages on a particular bin or storage location and instead of manually calculating the package content here the SSCC or SGTIN can be used to support the counting. So you can step by step provide all unopened SSCCs and SGTINs to the business function and the business function then will determine the complete hierarchy (all parents and childs) of the provided objects. All provided objects are marked as scanned and all child objects will be marked as derived. When providing a child object of an already provided parent object then an error message is issued as the parent is supposed to be unopened and thus the child cannot be scanned. Similarly when providing a parent object of an already provided object an error message is issued. The result of the business function is a big table that provides the complete hierarchy of all provided objects. The objects directly provided have the match indicator S (Scanned), the child objects of the directly provided objects have the match indicator D (derived) and all objects not provided do not have any match indicator which basically means that these objects are missing and further action is needed.

#### Inspect item

• This business function is a utility function that does not send an event message but it is a supporting function that can be used to identify an item (for example, SSCC or SGTIN). The function basically tries to decode the provided item and if it exists in the repository system the decoded information is returned.

#### Inspect Hierarchy

• This business function validates whether a child item belongs to a parent item. In case the parent item is an SSCC it can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided. If the percentage of child items is provided then the function validates whether the calculated amount of direct child items belongs to a parent item. The data is buffered even if the validation does not succeed. On saving, a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals. If the validation is not successful, the object event is sent for the top level object of the scanned hierarchy and the top level object of the hierarchy stored in the SAP Advanced Track & Trace for Pharmaceuticals repository.

#### **Aggregation Accuracy Check**

• This business function is a utility function that does not send an event message, but can be used to validate whether all SGTINs within the hierarchy are packed according to the data in the UoM. The data is buffered even if the validation does not succeed.

#### Sample

• This business function validates whether a particular SSCC or SGTIN can be used for sampling. If all validations succeed, the data is buffered. On saving, a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals. In the case of destructive sampling, the objects are de-commissioned.

#### Pack or Unpack LGTIN

• This business function validates whether a LGTIN quantity can be packed into / unpacked from a SSCC. For the parent it can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided. For the LGTIN quantity and UOM to be packed/unpacked must be provided. If all validations

succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Identify Parent**

• This business function is a utility function that does not send an event message but it is a supporting function that can be used to identify the parent object of an item.

#### **Request Object Control**

• This business function is a utility function that does not send an event message, but is a supporting function that can be used to request object control from other systems in a distributed system landscape with one central and one or more local SAP Advanced Track and Trace for Pharmaceuticals systems.

## **6.3.1.3** Outbound Processing Business Functions

#### Use

Given below are the Outbound Processing business functions

#### **Process**

#### Pick

This business function validates whether a particular SSCC or SGTIN can be picked. In case the item is an SSCC it can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided.
 Furthermore it can be checked whether the scanned items belong to a business transaction or alternatively the relation to a business transaction can be created. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### Pick to Pallet

This business function validates whether a particular SSCC or SGTIN can be picked and packed onto a
parentSSCC. For the parent it can be checked whether the SSCC corresponds to an HU with same ID if the
HU is provided. Furthermore it can be checked whether the scanned items belong to a business
transaction or alternatively the relation to a business transaction can be created. If all validations succeed
the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track
and Trace for Pharmaceuticals.

#### **Load Container**

This business function validates whether a particular SSCC or SGTIN can be loaded. In case the item is an SSCC it can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided.
 Furthermore it can be checked whether the scanned items belong to a business transaction or alternatively the relation to a business transaction can be created. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Ship Container**

This business function validates whether a particular SSCC or SGTIN can be shipped. In case the item is an SSCC it can be checked whether the SSCC corresponds to an HU with same ID if the HU is provided.
 Furthermore it can be checked whether the scanned items belong to a business transaction or alternatively the relation to a business transaction can be created. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

#### **Ship Document**

• The business function determines all serialized items that are related to a document and validates whether the items can be shipped. If all validations succeed the data is buffered. Upon save a corresponding EPCIS event is composed and sent to SAP Advanced Track and Trace for Pharmaceuticals.

## 6.4 Enriched Advanced Shipping Notification (eASN)

#### Definition

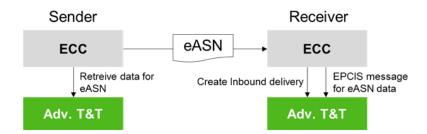
SAP Advanced Track and Trace for Pharmaceuticals offers two options to exchange serialized data with a subsequent supply chain partner

- Advanced Shipping Notification + EPCIS message
- Enriched Advanced Shipping Notification

This chapter deals with the enriched ASN of possibility 2. You can find more information on possibility 1 in the topic Outbound Processing [page 89].

The eASN is based on the new iDoc type /STTPEC/DELVRY05 - Advanced Track & Trace: Delivery Interface (enriched ASN) which contains serialized information and aggregation information in addition to the existing ASN structures.

The processing of the eASN is tightly integrated into the outbound and inbound process in ECC.



#### **More Information**

eASN Handling During Inbound Processing [page 193]

eASN Handling During Outbound Processing [page 192]

## 6.4.1 eASN Handling During Outbound Processing

When shipping an outbound delivery the serialized items and their hierarchies are queried from the repository system and an enriched ASN is composed that contains the serialized items and the packing hierarchy. The query is done based on the relation to the outbound delivery. So as a prerequisite all items to be shipped must have an object-transaction relation which for example, can be created by picking the items with reference to the outbound delivery.

## 6.4.2 eASN Handling During Inbound Processing

When receiving an eASN besides the creation of the inbound delivery also an EPCIS message to the repository system is composed and sent with following events

- Commissioning events for all shipped objects: Serialized Trade Items, Serialized Containers, and Lots that are referred within the Serialized Trade Items
- Aggregation events to compose the shipped hierarchy
- Shipping Event declaring the shipment of all top level objects (typically pallet SSCCs)

# 7 EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals

The EWM Add-on for SAP Advanced Track and Trace for Pharmaceuticals handles the necessary enhancements to ensure warehouse integration between EWM and SAP Advanced Track and Trace for Pharmaceuticals. The Add-On follows the same principles as the warehouse integration in SAP ECC based on SAP Warehouse Management (WM).

#### **Features**

- Master data integration and enhancement
  - o Master data integration is part of ECC Add-On
  - o Integration of Customers and Vendors as Business Partner
  - o Integration of Plants as Plant Locations
  - o Integration of Materials as Products
- Transactional data integration and enhancement
  - Integration of inbound deliveries and outbound deliveries and enhancement of delivery
  - o Integration of batch and enhancement of batch characteristics
- Warehouse Integration with Warehouse Toolbox and SAP Advanced Track and Trace for Pharmaceuticals functions
  - Warehouse business functions (activities) which include validation and buffering for a series of typical warehouse activities
  - Compose and send EPCIS event message for warehouse activity
  - Warehouse comfort functions such as get contents, get hierarchy, serial number request
  - Warehouse test UI enables testing of warehouse integration
  - RF demo implementation for picking of outbound delivery showcases potential usage of the toolbox

## 7.1 Master Data Integration and Enhancement

Certain master data needs to be present in EWM in order to enable standardized EPCIS based communication between EWM and SAP Advanced Track and Trace for Pharmaceuticals. EPCIS identifies trade items by globally unique GTIN and not by a proprietary material or product number. Similarly locations and business partners are identified via globally unique GLNs or SGLNs and not by proprietary location IDs or business partner IDs.

All master data objects in EWM already have the needed attributes. So this chapter mainly documents the measures and enhancements done for the integration from ECC via CIF.

#### Integration of Customers and Vendors as Business Partner

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals then the relevant business partners are also integrated from ECC to EWM via CIF. All relevant attributes are already integrated today (especially the GLN assigned to the business partner which is needed for EPCIS based communication). For more information, see the configuration guide at http://help.sap.com/attp.

#### Integration of Plants as Plant Locations

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals, then the plants are integrated as locations from ECC to EWM via CIF. Dependent on your process configuration, it may be necessary to maintain a GLN for the plant location in EWM in order to enable communication between EWM and SAP Advanced Track and Trace via the warehouse toolbox. Unfortunately the plant GLN is not automatically transferred via CIF from ECC to EWM and needs to be maintained separately in EWM. For more information, see the configuration guide at http://help.sap.com/attp.

#### Integration of Materials as Products

In case you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals then the material is integrated from ECC to EWM.

EWM however needs the GTIN to communicate via EPCIS with SAP Advanced Track and Trace for Pharmaceuticals via the warehouse toolbox .

In EWM the GTIN is stored by default in field EAN/UPC of the product master (tab *Units of Measure*). This field by default is integrated from the EAN/UPC field of ECC MARM structure.

SAP Advanced Track and Trace for Pharmaceuticals however uses the new field GTIN of the MARM extension as the EAN/UPC field in ECC is not clearly typed as GTIN.

Therefore within the ECC Add-On the CIF integration has been enhanced to integrate the GTIN from the MARM extension structure instead of the EAN/UPC field of MARM structure.

Only if the GTIN is not filled, then the old logic is executed which takes field EAN/UPC of MARM structure.

You can deactivate/change this enhancement implementation if you wish. If you deactivate it then you have the following options:

- Within EWM you can manually maintain the GTINs
- Within ECC you can maintain the same GTIN both in field GTIN and in EAN/UPC. The new transaction / STTPEC/TRD\_ITM\_SER Maintain trade item serialization attributes offers an action to synchronize the two fields. However, when following this option please consider that the EAN/UPC field in ECC cannot deal with leading zeroes. When you add a GTIN that starts with a zero, by default the zero will be removed and an inconsistent GTIN with too few digits will be integrated to EWM.

For more information, see the configuration guide at http://help.sap.com/attp.

## 7.2 Transactional Data Integration And Enhancement

#### Integration of Inbound Deliveries and Outbound Deliveries and Enhancement of Delivery

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals, then the relevant inbound and outbound deliveries are integrated from ECC to EWM.

To enable a standardized communication via EPCIS, the CIF interface and the delivery objects have been enhanced with the two attributes GLN and document year to enable encoding of business transaction ID in EPC URI format.

This integration just happens via standard delivery integration. No additional configuration is necessary.

Integration of Batch and Enhancement of Batch Characteristics

If you are using EWM and the EWM Add-On for SAP Advanced Track and Trace for Pharmaceuticals, then you have to ensure that certain batch attributes needed for serialization are also replicated as batch characteristics in ECC, as the standard way to handle batch attributes in EWM is via characteristics. Please find more information in the configuration guide at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a> on how to configure your solution in order to integrate the necessary attributes.

# 7.3 Warehouse Integration with Warehouse Toolbox and SAP Advanced Track and Trace for Pharmaceuticals functions

The warehouse integration with EWM follows exactly the same principles and paradigms like SAP WM. For more information, see Warehouse Integration [page 184].

The warehouse test UI can be accessed via transaction /STTPEW/WHS\_TOOLBOX - Warehouse Activity Test Client.

RF demo implementation

- The following demo scenario is available as part of the RF demo implementation
  - Outbound processing: Picking
- The RF demo is embedded into the standard EWM RF framework and tries to follow standard user interaction principles of EWM
- Please find further information regarding the configuration of the RF demo in the configuration guide at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>.

## 8 Operations Information

The following chapters cover topics that are related to the operation of SAP Advanced Track and Trace for Pharmaceuticals.

For general operations information, see the administrator's guide and configuration guides for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

#### i Note

SAP Note 2707616 ATTP System Setup & Best Practices is now available, which lists proposals and recommendations from SAP to help customers to set up and configure an SAP Advanced Track and Trace for Pharmaceuticals repository instance. We strongly encourage you to review this note to enable a proper system setup and prevent any issues from occurring.

For more information, see SAP Note 2707616.

#### **Related Information**

Archiving of Data [page 197] Integration of External Systems [page 209]

Usage of AIF Error Handling and Alerting for SAP Advanced Track and Trace for Pharmaceuticals [page 211]

## 8.1 Archiving of Data

Data archiving is used to remove mass data from the database that is no longer required in the system but must be kept in a format that can be analyzed. For all archiving objects of SAP Advanced Track and Trace for Pharmaceuticals , the data archiving concept is based on the Archive Development Kit (ADK). For more information, see the SAP NetWeaver Library on SAP Help Portal at <a href="https://help.sap.com/nw">https://help.sap.com/nw</a> . Open the product page for your SAP NetWeaver release and search for <a href="https://help.sap.com/nw">Archive Development Kit</a>.

Make yourself acquainted with the principles and functions of data archiving in SAP application systems. For more information, see Data Archiving in the SAP Netweaver library on SAP Help Portal at <a href="http://help.sap.com/nw">http://help.sap.com/nw</a>. Open the product page for your SAP NetWeaver release and search for <a href="https://bear.ncbi.nlm">Data Archiving</a>.

Additionally, Information Lifecycle Management (ILM) can be used for storage and destruction of expired archived data and files. For more information about SAP NetWeaver Information Lifecycle Management, see the user assistance available on SAP Help Portal at http://help.sap.com.

Make yourself acquainted with the principles and functions of Information Lifecycle Management in SAP application systems. Assistance of an ILM consultant is recommended to customize and make use of ILM in a correct way to build up the needs according to governance rules and regulations.

Archive business objects by using the respective archiving object. The following table shows the available archiving objects:

Business Object	Archiving Object
SAP ATTP: Archive Object Data	/STTP/OBJ
SAP ATTP: Archive Event Data	/STTP/EVT
SAP ATTP: Archive Transaction Data	/STTP/TRN
SAP ATTP: Archive Report Event Data	/STTP/REVT
SAP ATTP: Archive Serial Number Data	/STTP/SNLI

## 8.1.1 Archiving Object Data

#### **Definition**

The SAP Advanced Track and Trace objects are archived and deleted using archiving object /STTP/OBJ.

Before using the archiving object for the first time, you should check that the residence times for these objects are maintained in transaction SARA. Go to Customizing Residence Times of Objects.

Further, the retention times can be entered in transaction SARA. Go to Customizing Retention Times of Objects .

This is only necessary if ILM Retention Rules are expected to use the precalculated deletion date determined by SAP Advanced Track and Trace for Pharmaceuticals . Customarily, if ILM is switched on, the deletion date is calculated via ILM based on the rules defined in ILM Policies.

#### **Structure**

#### Table

When you use the archiving object  $/ \mathtt{STTP} / \mathtt{OBJ}$ , data is archived from the following tables:

Table Name	Description and Purpose
/STTP/DM_OBJ	Objects
/STTP/DM_OBJ_HLT	Object Hierarchy LGTIN Quantity Data
/STTP/DM_OBJ_HRY	Object Hierarchy

lable Name	Description and Purpose
/STTP/DM_OBJ_IDS	Object Identifiers (EPC)
/STTP/DM_OBJ_ARC	Objects Additional Archiving Data
/STTP/DM_OBJ_ITM	Objects (Serialized Items)
/STTP/DM_OBJ_LOT	Objects Lot (Level Objects)
/STTP/DM_OBJ_SCC	Objects (Serialized Containers)
/STTP/DM_EVT_REL	Event Relations to Objects
/STTP/DM_TRN_REL	Transaction Relations to Objects
/STTP/REP_OBJ_RL	Object Relations to Reporting Events

Description and Purpose

#### **Programs**

Table Name

The following programs are delivered for archiving object /STTP/OBJ.

Program	Function
/STTP/AR_DM_OBJ_PRE	Preprocessing Step of Archiving Process
/STTP/AR_DM_OBJ_WRI	Write Step of Archiving Process
/STTP/AR_DM_OBJ_DEL	Delete Step of Archiving Process
/STTP/AR_DM_OBJ_REL	Reload Data from Archive

#### **Preprocessing Program**

The preprocessing program checks the archivability of these objects. The following conditions are checked:

- Criteria relevant for objects of type Lot (Batch):
  - o Not referenced in any item-type object which is not yet archived or selected for archiving
  - Modified Time < current date customized "Lot Object Residence Time for Archiving" in days</li>
     OR
  - Expiration Date < current date customized expiration date horizon
- Criteria relevant for objects of type Serialized Trade Item (SGTIN):
  - Modified Time < current date customized "Item Object Residence Time for Archiving (Shipped)" in days
  - Logistic Status > 3 (shipped externally or sold or deactivated)
  - Not a parent in /STTP/DM\_OBJ\_HRY unless all child SAP Advanced Track and Trace for Pharmaceuticals objects are archived.
  - All objects from object hierarchy (above and below) are archivable. This criterion allows only full
    hierarchy archiving within one archiving session (hierarchy split between different archiving sessions is
    not allowed).

OR

- Modified Time < current date customized "Item Object Residence Time for Archiving (Not Shipped)" in days
- Logistic Status < 4 (not shipped)</li>
- Items are not aggregated. Every object selected must have pack status 0 (unpacked) and must not have any child objects.

OR

- Item belongs to a Lot which Expiration Date < current date customized "Horizon for Archiving of Expired Lots" in days
- Items are not aggregated. Every object selected must have pack status 0 (unpacked) and must not have any child objects.
- Criteria relevant for objects of type Serialized Container (SSCC):
  - Logistic Status > 3 (shipped externally or sold or deactivated)
  - Not a parent in <code>/STTP/DM\_OBJ\_HRY</code> unless all child SAP Advanced Track and Trace for Pharmaceuticals objects are archived.
  - All objects from the object hierarchy (above and below) are archivable. This criterion allows only full
    hierarchy archiving within one archiving session (hierarchy split between different archiving sessions is
    not allowed).
  - All objects will be considered as already archived if they are to be archived at the same archiving session.

To determine the conditions and time references of the entire hierarchy, the table <code>/STTP/DM\_OBJ\_ARC</code> was created and added to the Archiving Object <code>/STTP/OBJ</code>. If the ILM is switched on, the values from this table can be useful to create retention rules. The value determination follows the rules:

- In general, the following attributes are exposed to the ILM rules framework (or customer's own implementation) for deleting archive objects:
  - Country (condition)
  - Object Type (condition)
  - Creation Date (time reference)
  - Manufacturing Date (time reference)
  - Expiry Date (time reference)
  - Deletion Date (time reference)

The attributes are necessary for the *Write Step* to calculate the retention time and archive the objects grouped by conditions and the retention times.

- For objects that are **not** part of a pack hierarchy, the following determination rules apply:
  - $\circ$   $\,$  For SSCCs, only the object creation date is set (date from UTC timestamp only)
  - For SGTINs, the object creation date and the profile relevant country from the GTIN are set. Additionally, the Manufacturing Date and Expiry Date of the referenced LGTIN are set.
  - For LGTINs, the object creation date and the profile relevant country from the GTIN are set. Additionally, the Manufacturing Date and Expiry Date of the LGTIN itself are set.
  - Object type of the corresponding object is set.
- For objects that are part of a pack hierarchy, the following determination rules apply:
  - $\circ\quad$  All objects that are part of the hierarchy will get the same attribute values.
  - For all dates the maximum date (latest) from all included objects is set.
  - The country is determined based on the first detected GTIN. The reason is that, in case of mixed hierarchies containing multiple GTINs the likelihood is still high that they belong to the same country, as it is very rare that containers are packed or moved containing product units for different countries.

 If SSCCs contains SGTINs, object type Serialized Item is set, otherwise Serialized Container. For LGTIN Non-Serialized Quantity (Batch) is set.

Additionally, one more field <code>DELETION\_DATE</code> was created in the table <code>/STTP/DM\_OBJ\_ARC</code> to calculate the end of the retention time based on the values from the customizing table <code>/STTP/AR\_RTN\_OBJ</code> (ATT Archiving: Retention Time for Archiving Objects). The customer must not necessarily maintain this customizing table, if he doesn't not intend to make use of the field <code>DELETION\_DATE</code>. On the other hand, customer can configure their own retention rules either in ILM or implement their own archive deletion reports.

The following logic is used for the determination of the Deletion Date:

- The starting time of the calculation is the expiration date of the hierarchy or the object. If it's not provided, then the manufacturing date of the hierarchy or the object is used. If even that is not provided, then the creation date of the hierarchy or the object is used.
- To calculate the deletion date, the retention time is added to the starting time after the offset is added.

The provided BAdl can be used to calculate <code>DELETION DATE</code> anew, and so overrule the results of the rule described above.

#### Write Program

The write program supports the ADK interruption concept, that is, you can interrupt the write phase and continue it at a later point. For more information, see the SAP NetWeaver Library on SAP Help Portal at http://help.sap.com/nw . Open the product page for your SAP NetWeaver release and search for *Interrupting and Continuing Archiving Sessions*.

Without ILM, all instances could be even written to one file (if the size of a file is big enough) although the data may different.

If ILM is in use and ILM Policies are maintained, it is possible to group archiving data in files according to matching time references and condition fields. For each file, a retention time is calculated based on the Policy Rules and saved together with it for destruction to be run upon it.

#### **Delete Program**

The standard variants SAP&PROD (production mode) and SAP&TEST (test mode) are delivered for the delete program. The delete program does not delete the related entries in the tables:

- /STTP/DM OBJ IDS (will be needed later on; status is set to ARCHIVED)
- /STTP/DM EVT REL (will be archived and deleted by archiving object /STTP/EVT)
- /STTP/DM TRN REL (will be archived and deleted by archiving object /STTP/TRN)
- /STTP/REP\_OBJ\_RL (will be archived and deleted by archiving object /STTP/REVT)

#### **Reload Program**

The reload program is designed to reload data from archive back to database. The program uses the URN object code as a selection criterion for reloading. The program supports Test mode and Production mode as required by ADK concept. The reloading logic itself is supposed to be executed in the background task, therefore if the report is executed in the foreground, it will schedule a standard reloading background job automatically. The system can display the status of the scheduled job as well as application log from transaction SARA. The reload program reloads all the data (from all tables) linked to the selected object from archive.

- /STTP/DM OBJ
- /STTP/DM OBJ HLT
- /STTP/DM\_OBJ\_HRY

- /STTP/DM OBJ IDS
- /STTP/DM OBJ ARC
- /STTP/DM OBJ ITM
- /STTP/DM OBJ LOT
- /STTP/DM\_OBJ\_SCC
- /STTP/DM EVT REL
- /STTP/DM TRN REL
- /STTP/REP\_OBJ\_RL

Partial reloading is not possible.

#### General

A compact log with information about the data processed is written in all the preprocessing, write, delete and reload runs. Alternatively, you can enable the output of a detailed log containing additional information.

Progress confirmation is output in the job log and in the dialog (status line) at regular intervals in all the preprocessing, write, delete and reload runs.

#### **Enhancements**

If necessary, it is possible to replace the criteria for the archivability of an object by implementing the BAdI / STTP/BADI AR DM OBJECT.

## 8.1.2 Archiving Event Data

#### **Definition**

The events of SAP Advanced Track and Trace for Pharmaceuticals are archived and deleted using archiving object /STTP/EVT.

Before using the archiving object for the first time, you should check that the residence times for these events are maintained in transaction SARA. Go to Customizing Residence Times of Events.

Based on time fields like CREATION\_TIME, EVTTIME own time references can be created and used in ILM retention time rules. For more information, see the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at <a href="http://help.sap.com/attp">http://help.sap.com/attp</a>.

#### **Structure**

**Tables** 

When you use the archiving object/STTP/EVT, data is archived from the following tables:

# Table Name Description and Purpose /STTP/DM\_EVT Events /STTP/DM\_EVT\_PRP Additional Event Properties /STTP/DM\_EVT\_REL Event Relations to Objects /STTP/DM\_EVT\_SDR Event Relation to Source/Destination

#### **Programs**

The following programs are delivered for archiving object /STTP/EVT.

Programs	Function
/STTP/AR_DM_EVT_PRE	Preprocessing Step of Archiving Process
/STTP/AR_DM_EVT_WRI	Write Step of Archiving Process
/STTP/AR_DM_EVT_DEL	Delete Step of Archiving Process

#### **Preprocessing Program**

The preprocessing program checks the archivability of thes events. The following conditions are checked:

- CREATION TIME < current date customized residence time (days)
- Does not reference ATT objects that are not archived

#### Write Program

The write program supports the ADK interruption concept, that is, you can interrupt the write phase and continue it at a later point. For more information, see the SAP NetWeaver Library on SAP Help Portal at <a href="http://help.sap.com/nw">http://help.sap.com/nw</a>. Open the product page for your SAP NetWeaver release and search for *Interrupting and Continuing Archiving Sessions*.

If ILM is in use and ILM Policies are maintained, it is possible to group archiving data in files according to matching time references and condition fields. For each file, a retention time is calculated based on the Policy Rules and saved together with it for destruction to be run upon it.

#### **Deletion Program**

The standard variants SAP&PROD (production mode) and SAP&TEST (test mode) are delivered for the delete program.

#### General

A compact log with information about the data processed is written in all the preprocessing, write and delete runs. Alternatively, you can enable the output of a detailed log containing additional information.

Progress confirmation is given as an output in the job log and in the dialog (status line) at regular intervals in all the preprocessing, write, and delete runs.

#### **Enhancements**

If necessary, it is possible to replace the criteria for the archivability of an event by implementing the BAdl / STTP/BADL AR DM EVENT.

## 8.1.3 Archiving Business Transaction Data

#### **Definition**

The business transactions of SAP Advanced Track and Trace for Pharmaceuticals are archived and deleted using archiving object /STTP/TRN.

Before using the archiving object for the first time, you should check that the residence time for these business transactions is maintained in transaction SARA. Go to Customizing Residence Times of Transactions.

Based on time fields like CREATION\_TIME, MODIFIED\_TIME own time references can be created and used in ILM retention time rules. For more information, see the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

#### Structure

#### **Tables**

When you use the archiving object  $\slash\hspace{-0.05cm}$  TRN, data is archived from the following tables:

Table Name	Description and Purpose
/STTP/DM_TRN	Business Transactions
/STTP/DM_TRN_EVT	Business Transaction relations to ATT events
/STTP/DM_TRN_ITM	Business Transaction Items
/STTP/DM_TRN_REL	Business Transaction Relations to ATT objects

#### **Programs**

The following programs are delivered for archiving object /STTP/TRN.

Programs	Functions
/STTP/AR_DM_TRN_PRE	Preprocessing step of the archiving process
/STTP/AR_DM_TRN_WRI	Write step of the archiving process
/STTP/AR_DM_TRN_DEL	Delete step of the archiving process

#### **Preprocessing Program**

The preprocessing program checks the archivability of SAP Advanced Track and Trace for Pharmaceuticals business transactions. The following conditions are checked:

- MODIFIED\_TIME < current date customized residence time (days)
- Does not reference SAP Advanced Track and Trace for Pharmaceuticals objects that are not archived
- Does not reference SAP Advanced Track and Trace for Pharmaceuticals events that are not archived

#### Write Program

The write program supports the ADK interruption concept, that is, you can interrupt the write phase and continue it at a later point. For more information, see the SAP NetWeaver Library on SAP Help Portal at http://help.sap.com/nw . Open the product page for your SAP NetWeaver release and search for *Interrupting and Continuing Archiving Sessions*.

If ILM is in use and ILM Policies are maintained, it is possible to group archiving data in files according to matching time references and condition fields. For each file, a retention time is calculated based on the Policy Rules and saved together with it for destruction to be run upon it.

#### **Deletion Program**

The standard variants SAP&PROD (production mode) and SAP&TEST (test mode) are delivered for the delete program.

#### General

A compact log with information about the data processed is written in all the preprocessing, write and delete runs. Alternatively, you can enable the output of a detailed log containing additional information.

Progress confirmation is given as an output in the job log and in the dialog (status line) at regular intervals in all the preprocessing, write, and delete runs.

#### **Enhancements**

If necessary, it is possible to replace the criteria for the archivability of a business transaction by implementing the BAdl /STTP/BADI AR DM TRANSACTION.

## 8.1.4 Archiving Reporting Event Data

#### **Definition**

The reporting events of SAP Advanced Track and Trace for Pharmaceuticals are archived and deleted using archiving object/STTP/REVT.

Before using the archiving object for the first time, you should check that the residence time for these business transactions is maintained in transaction SARA. Go to Customizing Residence Times of Reporting Event.

Based on time fields like CREATION\_TIME, MODIFIED\_TIME own time references can be created and used in ILM retention time rules. For more information, see the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

#### Structure

#### **Tables**

When you use the archiving object /STTP/REVT, data is archived from the following tables:

Table Name	Description and Purpose
/STTP/REP_EVT	Reporting Events
/STTP/REP_OBJ_RL	Object Relations to Reporting Events

#### **Programs**

The following programs are delivered for archiving object/STTP/REVT.

Program	Function
/STTP/AR_REP_REVT_PRE	Preprocessing Step of Archiving Process
/STTP/AR_REP_REVT_WRI	Write Step of Archiving Process
/STTP/AR_REP_REVT_DEL	Delete Step of Archiving Process

#### **Preprocessing Program**

The preprocessing program checks the archivability of the business transactions. The following conditions are checked:

- MODIFIED TIME < current date customized residence time (days)
- STATUS REP EVT = "sent ok" or "error acknowledged"
- Does not reference SAP Advanced Track and Trace for Pharmaceuticals objects that are not archived
- Referenced SAP Advanced Track and Trace for Pharmaceuticals event is already archived

#### Write Program

The write program supports the ADK interruption concept, that is, you can interrupt the write phase and continue it at a later point. For more information, see the SAP NetWeaver Library on SAP Help Portal at http://help.sap.com/nw . Open the product page for your SAP NetWeaver release and search for *Interrupting and Continuing Archiving Sessions*.

If ILM is in use and ILM Policies are maintained, it is possible to group archiving data in files according to matching time references and condition fields. For each file, a retention time is calculated based on the Policy Rules and saved together with it for destruction to be run upon it.

#### **Deleting Program**

The standard variants SAP&PROD (production mode) and SAP&TEST (test mode) are delivered for the delete program.

#### General

A compact log with information about the data processed is written in all the preprocessing, write and delete runs. Alternatively, you can enable the output of a detailed log containing additional information. Progress

confirmation is output in the job log and in the dialog (status line) at regular intervals in all the preprocessing, write and delete runs.

#### **Enhancements**

If necessary, it is possible to replace the criteria for the archivability of a reporting event by implementing the BAdl /STTP/BADI AR REP EVENT.

## 8.1.5 Archiving Serial Number Data

#### **Definition**

Serial numbers of SAP Advanced Track and Trace for Pharmaceuticals are archived and deleted using archiving object /STTP/SNLI.

Before using the archiving object for the first time, you should check that the residence time for these serial numbers is maintained in transaction SARA. Go to Customizing Residence Times of Serial Numbers.

Based on time fields like TIME\_GEN, TIME\_REQ, TIME\_UPD own time references can be created and used in ILM retention time rules. For more information, see the configuration guide for SAP Advanced Track and Trace for Pharmaceuticals on the SAP Help Portal at http://help.sap.com/attp.

#### Structure

#### Tables

When you use the archiving object /STTP/SNLI, data is archived from the following tables

Table Name	Description and Purpose
/STTP/SNR_LIST	Advanced SNR Mgmt: Serial Number List
/STTP/SNR_LIST_A	Advanced SNR Mgmt: Serial Number Archive List

#### **Programs**

The following programs are delivered for archiving object /STTP/SNLI.

Program	Function
/STTP/AR_SNR_LIST_PRE	Preprocessing Step of Archiving Process
/STTP/AR_SNR_LIST_WRI	Write Step of Archiving Process
/STTP/AR_SNR_LIST_DEL	Delete Step of Archiving Process

#### **Preprocessing Program**

The preprocessing program checks the archivability of the serial numbers. The following conditions are checked:

- Time of creation or last update (TIME\_GEN, TIME\_UPD) < current date customized residence time (days)
- Serial number status (/STTP/SNR\_LIST-STATUS) = "2 Commissioned" or "3 Reported Lost"
- Range status (/STTP/SNR POOL-STATUS) = "3 Closed"

#### Write Program

The write program supports the ADK interruption concept, that is, you can interrupt the write phase and continue it at a later point. For more information, see the SAP NetWeaver Library on SAP Help Portal at <a href="http://help.sap.com/nw">http://help.sap.com/nw</a>. Open the product page for your SAP NetWeaver release and search for *Interrupting and Continuing Archiving Sessions*.

If ILM is in use and ILM Policies are maintained, it is possible to group archiving data in files according to matching time references and condition fields. For each file, a retention time is calculated based on the Policy Rules and saved together with it for destruction to be run upon it.

#### **Deletion Program**

The standard variants SAP (production mode) and SAP (test mode) are delivered for the delete program.

#### General

A compact log with information about the data processed is written in all the preprocessing, write and delete runs. Alternatively, you can enable the output of a detailed log containing additional information.

Progress confirmation is output in the job log and in the dialog (status line) at regular intervals in all the preprocessing, write, and delete runs.

## 8.1.6 Storage in ILM System

If ILM is switched on, after selection of an Archiving Object in the transaction SARA, the files created in the *Write* step can be moved to ILM Store (button Storage System).

## 8.1.7 Archive Destruction using ILM System

After retention time is exceeded, archiving files can be destructed through ILM. In this case the archiving files are physically deleted from the storage system.

#### **Enhancements**

If necessary, it is possible to delete data during destruction by implementing the BAdl  $\tt BADI\ ILM\ PRE\ DESTR\ FILE\ ACTION.$ 

### 8.1.8 Destruction of Object Data

To delete the IDs from the table <code>/STTP/DM\_OBJ\_IDS</code> the BAdl <code>BADI\_ILM\_PRE\_DESTR\_FILE\_ACTION</code> method <code>IF\_BADI\_ILM\_PRE\_DESTR\_FILE\_ACT~OPERATE\_ON\_DESTRUCTION</code> (Preparation for Clean Up Activity in a Remote System) is used. The implementation is done in enhancement implementation <code>/STTP/EH\_ILM\_PRE\_DESTR\_FILE\_A</code> , Class <code>/STTP/CL\_AR\_ILM\_PRE\_DESTR\_FILE</code>.

## 8.2 Integration of External Systems

#### **Definition**

SAP Advanced Track and Trace for Pharmaceuticals can interface with many external systems. The following scenarios show how this solution integrates with various external systems:

#### Integration

#### Interfaces with ERP, SAP ECC or WHS Systems

This solution offers interfaces for Master Data integration, Transaction Data integration and SAP Advanced Track and Trace for Pharmaceuticals functions mainly used for warehouse integration. These interfaces can be called from SAP ECC natively through the ECC Add-on for SAP Advanced Track and Trace for Pharmaceuticals. In addition, Third Party ECC and Warehouse Management systems can use the interfaces in order to integrate with this solution.

#### **Master Data Integration**

• These interfaces work based on RFC-based BAPIs to integrate Materials, Business Partners, and Locations. These BAPIs offer all entity attributes within their interface and hence you can create all master data entities externally.

#### **Business Transaction Document Integration**

• This interface is based on an RFC-based BAPI to integrate business transaction documents to SAP Advanced Track and Trace. The BAPI offers all attributes of the SAP Advanced Track and Trace Business Transaction. The ECC Add-on uses this interface to integrate production or process orders, inbound deliveries, outbound deliveries and return deliveries. Using the BAPI further document types (business transaction types) can be integrated as well in a custom implementation.

#### i Note

Batches are not integrated as master or transactional data through RFC but through EPCIS event containing LGTINs.

#### SAP Advanced Track and Trace for Pharmaceuticals Functions

- The ECC Add-on for SAP Advanced Track and Trace for Pharmaceuticals contains a toolbox to enable
  connection of the Warehouse functions to this solution. The Add-on contains comprehensive functionality
  in ECC and uses interfaces to SAP Advanced Track and Trace, which can be used by other systems as well.
  These interfaces are summarized as Advanced Track and Trace functions with the following main
  capabilities:
  - o Warehouse activity validation: Validates if warehouse activity is allowed for serialized items
  - o Warehouse functions: Provides functions such as Get contents, Get hierarchy and so on
  - eASN Support: Allows to query data from SAP Advanced Track and Trace for Pharmaceuticals to support composition of an enriched ASN containing all the serialized objects including their packing hierarchy.
  - Supports Serial number request
  - Supports Authentication Requests
  - Receives EPCIS event message

The repository system offers both RFC and OData Services for these Advanced Track and Trace functions. The ECC Add-on for SAP Advanced Track and Trace for Pharmaceuticals connects to the repository system via OData Services.

#### Interfaces with Government Systems

The communication with government systems typically is executed through SOAP service, especially for the country-specific functions of Turkey and Argentina. In case of China, there is a file based data exchange approach. For more details regarding the supported regulatory reporting messages, see Country-Specific Features [page 100].

#### Interfaces with Packaging Lines or Site- or Line Servers

Packaging lines, Site- or Line Servers can request serial number lists or ranges from SAP Advanced Track and Trace for Pharmaceuticals. Furthermore, there is a function to send serial number status information back from the packaging line to this solution, which enables reconciliation especially if the serial numbers are never to be commissioned. The serial number interfaces are both available as SOAP service and as RFC. This solution is capable of receiving EPCIS event messages from packaging lines through SOAP service or alternatively oData. It can also receive PML messages either through SOAP service or http post.

#### Interfaces with Supply Chain Partners

Supply Chain partners typically connect through SOAP service. The following interfaces are supported for this scenario:

- Request serial number range
- Request serial number list
- Send serial number range
- Send serial number list
- Send serial number status information (for both list and range)
- Receive serial number status information (for both list and range)
- Send EPCIS outbound message to subsequent
- Supply Chain Partner (contains following events: commissioning, aggregation, shipping)
- Receive EPCIS message from preceding supply chain partner
- Receive PML message from preceding supply chain partner

#### i Note

Sending of PML message is not supported

#### Interface with Local All

Local Alls are connected through SOAP service to the SAP Advanced Track and Trace system.

The connection to All is limited to the following interfaces:

- Send serial number range to All
- Receive EPCIS messages from AII

For more details, see Deployment Models [page 155].

#### Interface with Local Repository Systems

Central and local SAP Advanced Track and Trace systems are connected through an RFC connection. There are special interfaces available to connect a central SAP Advanced Track and Trace system with local systems that handle repository distribution, replication of transactional data, and serial number management. For more details, see Deployment Models [page 155].

# 8.3 Usage of AIF Error Handling and Alerting for SAP Advanced Track and Trace for Pharmaceuticals

#### AIF Error Handling and Alerting in General

SAP Advanced Track and Trace for Pharmaceuticals uses AIF standard functionalities for error handling and alerting of interfaces. More information about AIF and the available possibilities for error handling and alerting can be found in the AIF Application Help at <a href="http://help.sap.com/aif">http://help.sap.com/aif</a>.

## 8.3.1 Customizing of AIF Error Handling and Alerting in SAP Advanced Track and Trace for Pharmaceuticals

All available namespaces and assigned interfaces are predefined in SAP Advanced Track and Trace for Pharmaceuticals. As the settings for error handling and alerting are part of this Customizing these settings can't be changed on the customer system. Nevertheless SAP Advanced Track and Trace for Pharmaceuticals provides flexible capabilities to setup a customer-specific error handling and alerting.

#### **Details about Error Handling and Alert Customizing**

For all Interfaces a specific Standard Alert Receiver and a specific Alert Category is defined. The standard alert receiver enables customers to find specific alert receiver for each interface. The Alert Category provides the possibility to setup alert mails with interface specific content (for example, long texts). The provided alert categories can be changed by the customer using transaction Alrtcatdef. Example texts for the alert category are provided within the Configuration Guide.

More information about the Customizing settings can be found in the Configuration Guide at http://help.sap.com/attp.

#### Specific Error Handling and Alerting for EPCIS Interface

Besides the previously mentioned Standard Alert Receiver for each interface, SAP Advanced Track and Trace for Pharmaceuticals provides the possibility to set up a sender-specific error/alert handling for the EPCIS interface. That means it is possible to define a customer specific alert recipient for each sender that is used within the EPCIS inbound message.

More information on how to set up this sender-specific error/alert handling can be found in the section *Usage* of Sender Specific Alert Recipient Determination under Customer Specific Setup of Error Handling/Alerting [page 212]

More information about the Customizing settings can be found in the Configuration Guide at http://help.sap.com/attp.

## 8.3.2 Customer Specific Setup of Error Handling/Alerting

Assign Users for Standard Alert Recipient Determination

The assignment of users to the standard alert recipient needs to be done if specific users should be informed about a situation (this could be an error or warning message) during the processing of an interface. The definition of standard alert recipients is already predefined in SAP Advanced Track and Trace for Pharmaceuticals. That means only the assignment of users to the alert recipient must be done on the customer system.

To assign different interfaces and their standard alert recipients to a specific user, the transaction /AIF/RECIPIENTS can be used:

- Enter the user as Work Area.
- On the next screen enter the Namespace of the standard alert recipient
- Enter the message type

Message Types

Message Type	Result
N None	Alerts will be raised for Message Types E and A
I Info	Alerts will be raised for Message Types I, S, W, E and A
S Success	Alerts will be raised for Message Types S, W, A and E
W Warning	Alerts will be raised for Message Types W, E and A
E Application Error	Alerts will be raised for Message Types E and A
A Technical Error	Alerts will be raised for Message Types E and A
' 'Application Error or Technical Error	Alerts will be raised for Message Types E and A

• Set the flag Overview – this will control that the alert recipient is displayed within the AIF Interface Monitor

After you have saved the assignment of the Namespace / Alert Recipient to the user this user will receive alerts. These alerts are visible within the AIF Interface Monitor (Transaction /AIF/IFMON). For more information, see Usage of the AIF Interface Monitor [page 215]. In case that the Mail Server is setup on your system and the user has an email address assigned an alert mail will be send to the user.

#### → Tip

If you have trouble with the determination of the standard recipient, ensure that the AIF default recipient *ALL* is not used for all interfaces. To check that AIF Default Recipient *ALL* is used/not used, do the following:

- Call transaction SM30, enter view name /AIF/V ALRT DET
- Leave Namespace, Interface and Version empty and press Enter
- Confirm the next popup with CONTINUE
- If the following entry is displayed, the AIF Default recipient determination is active:

Checking AIF Default Recipient Determination

Interface Specific Set-
tings

Namespace	Interface	Version	Recipient for Alert
			ALL

• To use the standard alert recipient you have to delete the recipient ALL

#### Usage of Sender Specific Alert Recipient Determination

For the EPCIS Inbound Interface, SAP Advanced Track and Trace for Pharmaceuticals provides the possibility to set up the alert recipient determination based on the sender. This setup is an additional feature to control the alert recipient determination in a more specific way. That means, you can assign one or more users to the standard recipient of the EPCIS interface, but for a specific sender you can determine a specific alert recipient and assign specific user just to the alert recipient of this sender.

To set up the sender specific alert recipient, do the following:

- Create customer-specific namespace, for example, ZALERT. Call transaction /AIF/CUST and then go to Customizing for Define Namespace under SAP Application Interface Framework Interface Development
- 2. Create customer-specific alert recipient for the created namespace ZALERT. Call transaction /AIF/CUST and then go to Customizing for *Define Namespace-Specific Features* under SAP Application Interface Framework Frror Handling. In this Customizing activity, navigate to Define Recipients to define the sender specific alert recipients. For example, AR MUELLER, AR SCHMITT.
- 3. Then assign the sender-specific Alert Recipients to the Interface /STTEI/EPCIS\_MSG. Call Transaction / STTP/ART INB SENDER to maintain the following:

Namespace	Interface Name	Interface Version	Namespace Recipient	Recipient for Alert	Sender of Mes- sage
/STTEI	EPCIS_MSG	1	ZALERT	AR_MUELLER	PAR_MUELLER
/STTEI	EPCIS_MSG	1	ZALERT	AR_SCHMITT	SER_SCHMITT

→ Tip

For Sender of Message, the sender of the message should be entered with prefix 'SER\_' for serialized processing, and prefix 'PAR\_' for non-serialized processing.

With the above settings Recipient AR\_SCHMITT is determined for serialized EPCIS messages from Sender SCHMITT. For non-serialized EPCIS messages from sender MUELLER alert recipient AR\_MUELLER is determined.

For all other senders of EPCIS messages the default recipient /STTP/AR EPCIS MSG will be determined.

4. Finally, assign a user to the sender-specific alert recipient. This can be done by calling transaction /AIF/ RECIPIENT. Note that within /AIF/RECIPIENT the customer-specific namespace ZALERT must be used.

#### Usage of Message Specific Recipient Determination

Besides the above mentioned 'Standard Recipient Determination' and the 'Sender Specific Recipient Determination', SAP Advanced Track and Trace for Pharmaceuticals provides the possibility to determine a recipient based on specific messages posted during interfaces processing. Below you can see how this can be setup based on the message W276 – this message is a warning to inform the user that the event might not be the newest for some object.

Setting up Alerting for Message W276:

1. Call transaction / STTP/ART MSG and enter the following values:

Setting up Alerting for Message W276

Namespace	Interface Name	Interface Version	Namespace Recipient	Recipient for Alert	Msg Type	Message Class	Message Number
/STTEI	EPCIS_MSG	1	ZALERT	AR_MSG	W	/STTP/ DM_MSG	276

→ Lip

Namespace ZALERT must be defined in advance. AR\_MSG must be defined in customer specific namespace ZALERT.

- 2. Then assign a user to the sender alert recipient AR\_MSG. Call transaction /AIF/RECIPIENT. Note that within /AIF/RECIPIENT the customer-specific namespace ZALERT must be used.
- 3. Before you use the message-specific recipient determination , check that the *General Customizing Table* contains correct settings for parameter AIF\_ALERT\_MESSAGE. For more information regarding this parameter see *General Customizing* in the Configuration Guide at http://help.sap.com/attp.

For more information about the customizing settings, see the configuration guide at http://help.sap.com/attp.

#### **Customer Specific Alert Recipient Determination**

If the above ways of determining alert recipients are not sufficient to fulfill your specific business requirements, the enhancement spot/AIF/ALERT provides the BAdI /AIF/ALERT\_DET\_RECIPIENTS. This BAdI lets you implement a customer-specific redetermination of alert recipients. For redetermination, it is required that at least one recipient has already been determined. If no recipient is found, the BAdI is not called.

## 8.3.3 Usage of the AIF Interface Monitor

The AIF Interface Monitor (transaction /AIF/IFMON) provides a user-specific overview about the interfaces and the alert recipients assigned to the user.

Recipients used in the alert recipient table, as well as the standard recipient, are displayed in the AIF Monitor if the flag *Overview* is set in transaction /AIF/RECIPIENTS. If the BADI is used to add recipients in specific situations, this recipient will not be displayed in the AIF Monitor. For the EPCIS interface it is possible to display this recipient by adding the recipient to the *Recipient assignment table* with a sender that will never exist.

If an alert is raised, this status is indicated by an active alert icon.

In column *Mail* the user can set up the mail notification for each recipient. The following setup is possible:

Icon	Icon Text	Mail Notification
<b>2</b>	No mail	The user will not get notifications via mail for this recipient
<b>1</b>	Mail for next alert	The user will get notifications via mail for the next alert. That means the user will get a mail if an alert is raised. The user will not get any further mails until the existing alert is confirmed and a new alert is raised.
S <sub>B</sub>	Mail for every error	The user get notifications via mail for all alerts (also if there is an existing alert) with Message Type A or E.

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