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Integrating LIMS Into a Large-Scale Manufacturing Environment

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Global science-based organizations, under increasing pressure to harmonize their business processes, are seeking ways to standardize mission-critical computing systems such as LIMS, and to integrate these with enterprise platforms and systems. Different sectors within the same organization often employ information management systems from a variety of vendors for the same purpose. Industry mergers and acquisitions have only exacerbated this. Thus, it is no surprise that the standardization and integration of systems account for nearly 30% of IT budgets.

Scientists are primarily concerned with gathering raw observation and data and refining these into information that can be used to make strategic business decisions. Therefore, LIMS are evolving beyond lab-centric sample and report management tools and are increasingly tied to broader business processes. Organizations now view LIMS as strategic solutions that play a pivotal role in the integration and distribution of scientific information throughout the global enterprise.

This is particularly the case in large-scale, multisite production environments, in which the rapid transfer of reliable, quality-related laboratory data throughout an organization facilitates earlier and better-informed decisions. This allows processes to be optimized, quality control improved, and resources to be more effectively deployed. Ultimately, the organization benefits by bringing products to market faster, maintaining a competitive edge and achieving a higher return on investment.

LIMS and knowledge management

An important reason that organizations opt to integrate LIMS into their corporate systems is the rapid availability of scientific information for access and reporting across both geographic and business boundaries. The development and management of knowledge—a process based on sharing information in such a way that group learning is facilitated—is a particularly high-profile issue in the R&D environment. Making data and the derived conclusions readily available to managers and decision-makers in the organization greatly improves its ability to exploit new scientific developments and maintain a competitive edge.

Within the manufacturing environment, knowledge management has a more immediate benefit. Effective data sharing and mining can promote innovative ways to analyze samples and predictive models. New algorithms can be developed to extract information from the large body of laboratory data. These can prove invaluable for improving manufacturing efficiency and quality control, as well as for accelerating product development. In addition, modern analysis tools can be used to construct models for closed loop control and optimization to provide reduced waste and cycle times, higher product yields, and faster scale-up of production.

LIMS integration can be the key to establishing an enterprise-wide quality infrastructure. Although manufacturing data have historical value, the true benefit to integrating production and quality functions results from the immediate, short-term knowledge of the process that derives from collecting parameters from disparate enterprise applications, for example, throughout a 20-hr cycle, from raw material to finished product. Standardized, integrated systems provide flexibility and reduced running costs, while LIMS integration with plant control systems can help eliminate bottlenecks in the production process.

Automation within the laboratory

Laboratories operating a lab-centric LIMS are not much more effective than laboratories with paper-based procedures in terms of sharing information with the wider enterprise. The deployment of a LIMS is usually the first step taken toward automating laboratory processes. In addition, chromatography data system (CDS) integration is typically among the first interfaces addressed within the lab-centric environment, since as much as 50% of a laboratory's results are commonly generated from chromatography instruments. A typical lab-centric LIMS offers instrument integration, reporting capabilities, and resource planning functionality. Although efficiency and control within the laboratory are increased, few benefits are realized for the broader organization. This situation may be adequate in environmental testing laboratories, for example, in which the laboratory report is the finished product. Such is not the case for a batch of polyethylene or a strip of paracetamol that is shipped to a customer.

The lab-centric LIMS connects to the wider enterprise only in terms of human interfaces. Sample requests from the manufacturing process, for instance, are logged manually; parameters are entered by hand; and quality decisions are made only after a suitable report has been generated. These manual processes highlight areas in which inefficiency, inaccuracies, and bottlenecks can occur, especially when the individual or team that provides this interface is unavailable, whether due to illness, vacation, or workload. The cost of these inefficiencies can be significant—especially when they occur at multiple sites within the global organization.

The semi-integrated laboratory

Traditionally, systems integration has focused on enabling communications between two discrete systems. The real challenge, however, is to permit effective communication among the enterprise's many different systems. Organizations strive to ensure tight quality control throughout their business processes and compliance with strict regulatory requirements—from material delivery through production, packaging, and distribution to worldwide customer service. As a result, quality management departments are under increased pressure to deliver quality-related information to an ever-widening range of stakeholders throughout the enterprise.

Integrating LIMS with Enterprise Resource Planning (ERP)

In large manufacturing environments, ERP systems from suppliers such as SAP Software AG (Walldorf, Germany) and PeopleSoft Inc. (formerly JD Edwards) (Pleasanton, CA) are considered the integration hub for other systems. This view of ERP is understandable since it has evolved such that it now impacts every area of business.

In the QA laboratory of a production facility, the initial step for assigning work to the laboratory starts in the ERP system, typically triggered by warehouse stock levels. This is transformed into a work order for production, which in turn simultaneously prompts the LIMS to make a quality assessment and the Manufacturing Execution System (MES) to produce the material according to the specification. In this example, both LIMS and MES are remote to each other, and communication between the systems is via the ERP.

To solve this obvious bottleneck, some organizations use human interfaces from QA and/or Production that access the systems to review data and ensure that timely decisions are made based on the quality or process data. A typical interaction between the LIMS and ERP is to download the quality data plus any reference data to LIMS, and to upload either summary results or disposition decisions to ERP. Once a quality manager enters results in the LIMS and the parameters are checked, they can be automatically sent to the ERP for further processing. Either the LIMS or ERP can be the trigger for usage decisions regarding product disposition, delivery, or shelf life.

To facilitate the distribution of consistent quality information throughout the organization and to enhance operational efficiencies, some LIMS vendors have introduced standard interface solutions to integrate LIMS with leading ERP systems, such as the Enterprise R/3 (SAP Software AG). This type of interface solution requires a specialist, functionally rich enterprise-centric LIMS to expedite the bi-directional data flow between the laboratory and manufacturing, streamline data handling, and integrate data collection and reporting.

Modern interfaces have become increasingly flexible and user friendly. Progressive LIMS vendors, for example, have developed user-driven mapping functions as part of their ERP integration solutions. These offer the LIMS user easy access to required information from the ERP in a format that relates directly to LIMS entities with which they are familiar. Advanced inspection point processing functionality allows inspection points to be created within the LIMS via a configurable mapping process so that recognizable data objects can be sent, for example, to the R/3 quality management module. Upgrades of the ERP system require only a simple reconfiguration of the objects in the LIMS interface.

Integrating LIMS with Process Information Management Systems (PIMS)

A further integration step is to interface the LIMS data with PIMS from vendors such as OSIsoft Inc. (San Leandro, CA), Honeywell International Inc. (Morristown, NJ), Yokogawa Electric Corp. (Tokyo, Japan), and AspenTech Technology Inc. (Cambridge, MA). This allows on-line/at-line process information to be matched with off-line tests, typically by using sampling point and time stamps to match the tags within the PIMS. The obvious benefit is that it becomes possible to compare on-line analyzer results with analytical data generated within the laboratory, thus speeding the process and allowing timely corrective action to be taken.

Modern LIMS–PIMS integration solutions can provide real-time delivery of quality-related data for plant- and enterprise-wide monitoring and analysis purposes. Validated analytical information is directly and immediately available to the systems and managers involved in the manufacturing process, resulting in better control of process plant operations, reduced product loss, and greater productivity. As discrete measurement data are transmitted to PIMS, plant engineers or operators can analyze and track data trends and make decisions based on data from different locations throughout the production process. Correlations can be drawn between operational parameters in the process and QC data in the LIMS, enabling plant engineers to make adjustments to parameters before they have a chance to impact product quality. Poor product quality results from the laboratory, for instance, may necessitate changes to a reactor's operating temperature, and timely action is critical to reducing waste and associated down time.

Samples obtained from the discrete sampling points and taken to the laboratory are logged into the LIMS; once the samples have been analyzed for the predefined test, they are sent in a secure manner to the PIMS. Modern solutions allow results to be sent based on any criteria defined by the user. Discrete and continuous measurement data can be retrieved from PIMS into the LIMS—samples can be logged into the LIMS, for example, when a certain limit is exceeded in the PIMS, so that the analyst or engineer can easily identify trends. Transferring data from the PIMS to the LIMS also allows the data to be accessed by other corporate systems that interface to the LIMS, such as ERP.

Until recently, the interfacing of LIMS and corporate systems has been considered by many to be full integration, since point solutions, reconfiguration, or upgrading is required when new versions of either system are deployed. However limited, there also remains an element of human interaction with the data. Further, although communication among the systems is virtually instantaneous, the information is still available only in separate systems.

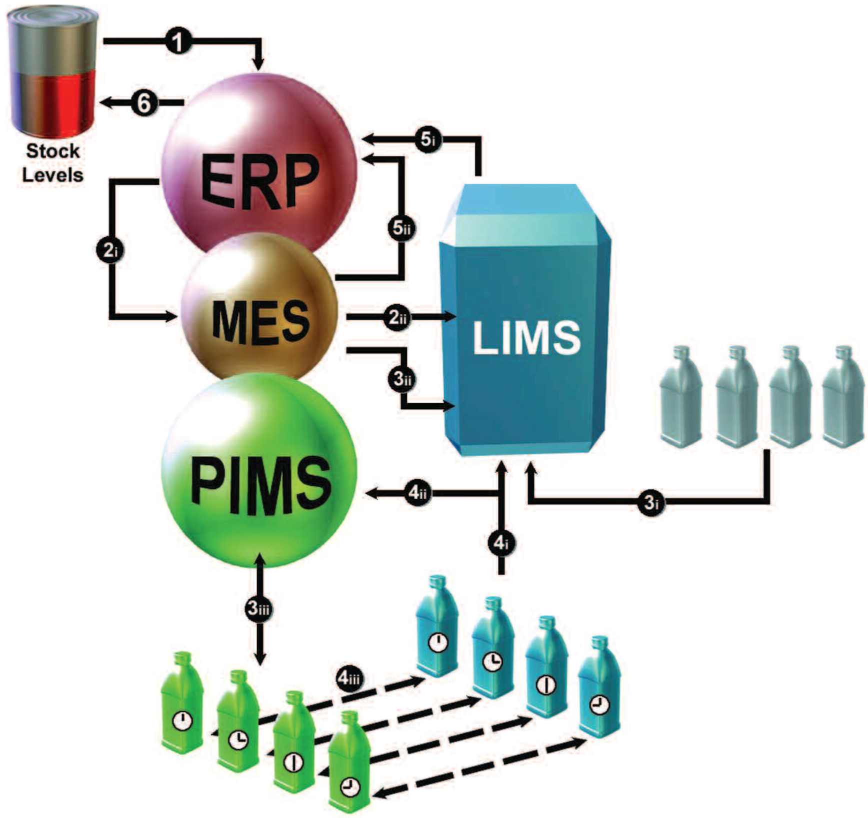

Figure 1 Integrated LIMS/ERP/PIMS/MES architecture within a large-scale manufacturing environment. Key—1) ERP: stock levels trigger manufacturing request. 2i) ERP: triggers production order in MES. 2ii) ERP: triggers quality process in LIMS. 3i) Samples logged into LIMS for designated stages of production. 3ii) MES: process parameters and specifications sent to LIMS. 3iii) PIMS: monitors on-line results. 4i) LIMS: samples taken at correct times. 4ii) PIMS: production parameters stored. 4iii) LIMS results compared with PIMS results (MES: outliers trigger LIMS investigation samples). 5i) LIMS: QA check results and disposition at end of production, generates Certificate of Analysis and sends to ERP. 5ii) MES generates batch record and sends to ERP. 6) ERP: adds batch to stock levels and clears for shipment.

The fully automated laboratory

A fully integrated scenario allows single data entry points (e.g., data entered into one system) to become available within other enterprise systems as required. Examples of this include: a result in LIMS that elicits a decision in ERP, an out-of-specification result in PIMS that initiates an investigation sample in LIMS, or a change to an ERP specification that triggers updates in LIMS or MES. Figure 1 illustrates interaction and integration between these applications and a typical flow of information. The SampleManager LIMS (Thermo Electron Corp., Woburn, MA) offers the capability for ERP and PIMS integration.

The role of Web services

Web services are another important component of the system for organizations seeking to integrate and leverage their informatics solutions. A Web service is simply an application that can be delivered as a network service and integrated using standard

Internet technologies. Much of the strength of the Web services concept lies in the fact that it combines a simple-to-understand format with proven and well-established communications technology.

Web services are built using a group of XML (eXtensible Markup Language) standards, thereby providing complete platform independence. This allows an organization to deploy the Web service on the server platform of its choice, and to use the Web service from any application written in any programming language. Applications can be Web-based or thick clients; the only requirement is the ability to manipulate XML and to post it to an Internet URL or internal intranet.

Given this flexibility, it is no surprise that many corporations are looking to utilize XML-based Web services as the means to integrate a multitude of applications built on disparate technologies. To accomplish this, however, the solution design must go beyond simply adding Web interfaces to existing applications for data accessibility. While providing user access across geographic and business boundaries brings distinct advantages, this should not be confused with the process efficiencies and productivity to be gained from truly integrating the various systems within the organization. A Web browser with a modern interface will provide access to applications on the network, but it will not necessarily provide data integration and communication.

With the advent of Web-based clients, it is now possible for systems to be integrated at the client level using a hybrid Web interface, which allows users from multiple disciplines to interact with the parts of each system that are relevant to them, using a common mechanism. An example is the ability to see process parameters and analytical trends in the same Web view, and to make a disposition decision in ERP from an authorization in LIMS.

The union of XML and HTTP, as a platform-independent way for applications to communicate, has been given the acronym SOAP (Simple Object Access Protocol). Web services and SOAP are superseding previous methods for exchanging business data, such as Electronic Data Interchange (EDI). Leading LIMS vendors are looking toward delivering Web services solutions using a secure SOAP-based architecture. Integration is provided by tried and tested Internet communication protocols. TCP/IP, HTTP, and SMTP can all be used, and are the backbone technologies of the Internet. These technologies are very well established and are widely supported, thereby helping integration and platform independence.

A truly integrated informatics framework

If all applications within the enterprise are interfaced using a common standard, it becomes a much simpler operation to add additional applications, or to upgrade or replace applications, without also requiring significant remediation of the interfaces. This approach also significantly increases the flexibility of large multisite organizations, since it becomes possible to exchange data between systems. This would allow, for instance, the transfer of a manufacturing process to an alternate site should business reasons deem it necessary to move production to a different geographical region. Changes or additions to enterprise systems become manageable (e.g., replace the PIMS, add in accounting system) since the integration uses a common framework rather than a point solution. The same data format is, in effect, passed around each system with the individual interfaces choosing the relevant data within the set. This opens up the potential of a truly integrated informatics framework and brings it within the realm of possibility.

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