U.S. FOOD & DRUG ADMINISTRATION

Request for Information and Response Cover Sheet

RFI #	FDA-RFI-20-1224848	
RFI Title	Regulatory Business Information Services (RBIS) Systems Integration and Support, Request for Information	
RFI Due Date	Thursday, May 14, 2020at 3:00 PM EST (5-page limit)	
Company	Name	
	Website URL	
	Address	
	Phone	
	DUNS Number	
	Size Status/number of employees	
	How product can be procured?	
Contact	Name	
	Email Address	
	Address (if different from company address)	
	Phone Number	
	Cell Number (optional)	
	Fax Number (optional)	
Focus Areas included in response	Master Data Management	
	Data Warehouse and Reporting	
	Big Data and Predictive Analysis	
	Machine Learning	

U.S. FOOD & DRUG ADMINISTRATION

Request for Information

"This is a Request for Information (RFI). This is NOT a solicitation for proposals or quotations. This notice is for information, planning and market research purposes only and shall not be construed as either a solicitation or obligation on the part of the Food and Drug Administration or its Centers."

Responses to this RFI will be treated as information only. This RFI is solely for gathering information and is not a Request for Quotation or a Request for Proposal (RFQ/RFP). Responses to this notice cannot be accepted as offers. No entitlement to payment of direct or indirect costs or charges by the Government arises as a result of submitting responses to this RFI or the Government's use of submitted information.

The Government will not return responses to this RFI.

Background

The Food and Drug Administration's (FDA's) mission is to protect the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. Several Information Technology (IT) systems have been created to meet mission critical requirements as well as meet the requirements imposed by executive orders. The Office of Regulatory Affairs (ORA) systems assist FDA personnel in tracking and managing the field activities throughout the regulatory process for inspecting manufacturers and their products, conducting sample analyses, and reviewing imported products offered entry into the country to ensure the compliance with FDA regulations. Furthermore, ORA systems support other FDA Centers in the evaluation of the premarket products, work planning activities to identify high risk firms, and in developing new policies.

General Information

The Regulatory Business Information Services (RBIS) is a major investment that supports FDA's regulatory mission. RBIS applications include master data management, data warehouse, reporting, analytics, and enterprise search for FDA and for the Office of Regulatory Affairs (ORA). The purpose of the RBIS investment is to deliver integrated and validated Enterprise-wide critical data from various FDA and non-FDA data sources. ORA Imports, Systems for Inspection, Recalls Compliance, and Enforcement (SIRCE), Automated Laboratory Management (ALM), and Food Safety Modernization Acts (FSMA) systems and other Centers systems rely directly on RBIS services. RBIS is the primary source for the historical information that has been collected via ORA Imports, SIRCE, and ALM and provides integrated regulatory and compliance data in support of

data management, business intelligence, searching, trending, and analytics. The FDA is seeking innovative solutions from respondents to the RFI. A complete response to the RFI should include answers to all the questions. Responses should include industry and federal examples of the respondent's best practices, when possible. Responses should include a thorough level of detail of all described technologies and how they can improve the RBIS Systems Integration and Support.

Questions regarding this notice should be submitted by 3:00 pm Eastern Time May 14, 2020 and may be answered within two weeks of submission. No basis for claims against the United States government shall arise as a result of a response to this request for information or from the United States government's use of such information. Proprietary, classified, confidential, or sensitive information should not be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s). As part of its market research, the Government also reserves the right, but is under no obligation, to meet with or make subsequent inquiries to any firm to gain additional information on Industry best practices.

Responses of no more than 5 pages should be emailed to Tiffany.Hatcher@fda.hhs.gov no later than 3:00 pm Eastern Time May 14, 2020.

Objectives

The FDA is seeking a contactor to innovate and enhance program applications while maintaining services for existing RBIS users.

Questions to be answered

1. Please provide documentation of the size of your business. If you are classified as a small business, Historically Underutilized Business Zone small business, Service-Disabled Veteran Owned Small Business, Woman-Owned Small Business and/or SBA 8(a) certified small business, please provide a capability statement in addition to the other information for acquisition strategy determination. Additionally, please demonstrate your firm's capability to meet the requirements of FAR 52.219-14, Limitations on Subcontracting.

2. Have you use subcontractors in the performance of services detailed in the draft BPA SOW task areas attached? If so, provide a rough estimate of how much of the work performed was completed in house versus subcontractors out for additional resources?

3. Does your organization have an existing GSA schedule for these types of services outlined in the draft BPA SOW? If so, please provide the information.

4. Describe your experience in the development of mobile applications. What were some of your challenges and how did you overcome them?

5. Describe your experience in the development of master data management. What were some of your challenges and how did you overcome them?

6. Describe your experience in the development of data warehouse and reporting, business intelligence, analytics, and enterprise search. What were some of your challenges and how did you overcome them?

7. Describe your experience in the development of predictive analysis and using Natural Language Processing and Artificial Intelligence/Machine Learning. What were some of your challenges and how did you overcome them?

8. Describe your experience in the development of Big Data implementations specifically using Hadoop Ecosystem, Spark, Docker, DevOps, Microservices, Elastic Search and related tools. What were some of your challenges and how did you overcome them?

9. Describe your experience Cloud migration and implementing solutions in GovCloud with integration with On Prem data. What were some of your challenges and how did you overcome them?

Place of Performance

The majority of the work shall be performed both offsite at the Contractor's facility as well as the government's White Flint North Office. Additionally, the Contractor shall attend meetings held at various FDA locations within the Metro DC commuting area.

Attachments

Draft Statement of Work

HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NEXT GENERATION OF REGULATORY BUSINESS INFORMATION SERVICES (RBIS) SYSTEM INTEGRATION SERVICES

Blanket Purchase Agreement (BPA)

Statement of Work (SOW)

1. General Information

The Food and Drug Administration's (FDA's) mission is to enforce the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws that are designed to protect consumers' health and safety. Several Information Technology (IT) systems have been created to meet mission critical requirements as well as meet the requirements imposed by executive orders. The Office of Regulatory Affairs (ORA) systems assist FDA personnel in tracking and managing the field activities throughout the regulatory process for inspecting manufacturers and their products, conducting sample analyses, and reviewing imported products offered entry into the country to ensure the compliance with FDA regulations. Furthermore, ORA systems support other FDA Centers in the evaluation of the premarket products, work planning activities to identify high risk firms, and in developing new policies.

The Regulatory Business Information Services (RBIS) is a major investment that supports FDA's regulatory mission. RBIS applications include master data management, data warehouse, reporting, analytics, and enterprise search for FDA and for the Office of Regulatory Affairs (ORA). The purpose of the RBIS investment is to deliver integrated and validated Enterprise-wide critical data from various FDA and non-FDA data sources. ORA Imports, Systems for Inspection, Recalls Compliance, and Enforcement (SIRCE), Automated Laboratory Management (ALM), and Food Safety Modernization Acts (FSMA) systems and other Centers systems rely directly on RBIS services. RBIS is the primary source for the historical information that has been collected via ORA Imports, SIRCE, and ALM and provides integrated regulatory and compliance data in support of data management, business intelligence, searching, trending, and analytics.

While the RBIS applications are mature and continue to meet the growing reporting and data needs of ORA and Center users, FDA seeks to continue to innovate and enhance the program applications while maintaining services for our existing users. Thus, FDA seeks development, modernization and enhancement support in addition to operations and maintenance support through this BPA.

2. Background

The three primary components of RBIS are 1) FDA's Inventory of Data Assets (FIDA) which includes management of the firms hub domain and associated services and 2) Business Intelligence and Analytics for data warehousing which includes reporting, dashboards, and mapping capabilities via the Online Reporting Analysis and Decision Support System (ORADSS) and Tableau and 3) Big Data Analytics which includes Online Search and Retrieval (OSAR)/Firm360, Center Views and Resource Library. All three components are critical to supporting ORA and FDA's regulatory activities.

Figure 1 depicts a high-level overview of the entire RBIS program.

RBIS Systems

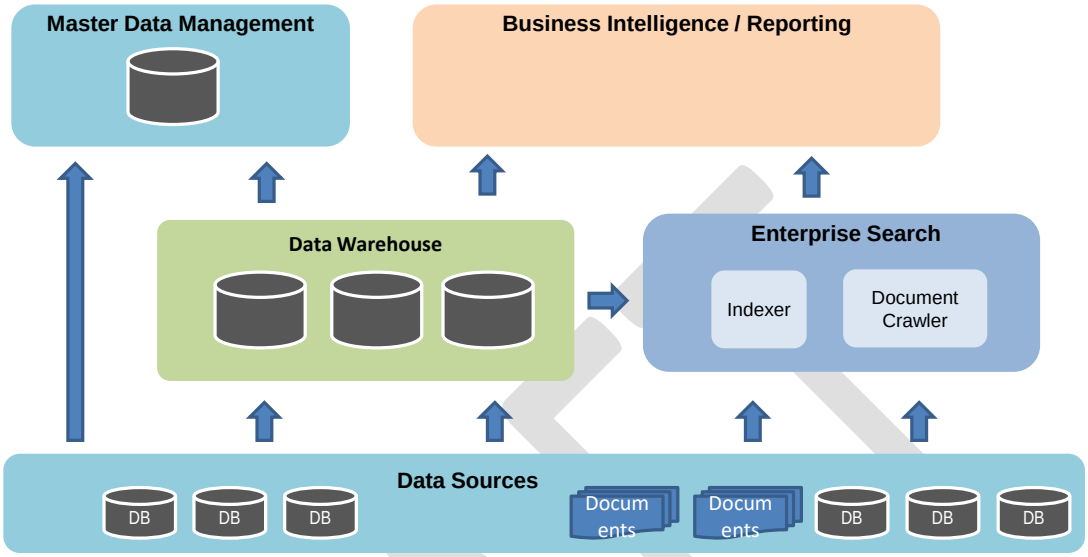

Figure 1 Overview of RBIS Program of Applications

The first major component of RBIS is the Firms Data Management System known as FIDA (FDA Inventory of Data Assets). FIDA includes support for an integrated, worldwide view of industry information consisting of both foreign and domestic firms and operations data. FIDA's data and services are critical to providing ORA and the Centers with data for program planning and evaluation, surveillance trending, management information reports, and scientific analysis. FIDA leverages Informatica's COTS tool for Master Data Management (MDM) to manage over 13M domestic and foreign firms in the ORA inventory. FIDA provides Data Quality services and Web Services for Address Validation and Firm Matches by FEI, Name and Address, DUNS number, and Registration Numbers, including strict and fuzzy matches. It integrates with Dun & Bradstreet monthly to match with the ORA Firm Inventory based on Name and Address, maintaining a crosswalk between FEI and DUNS. FIDA also accesses Dun & Bradstreet's integration web service on a real time basis. FIDA also transfers FURLS Registrations to FMS. Numerous ORA and Center systems utilize FIDA Web Services including FMS, ACE/IWS, PNM, OASIS, ITACS, eDRLS, CDRH Centry, CBER HCTERS and FURLS modules. (see Figure 2).

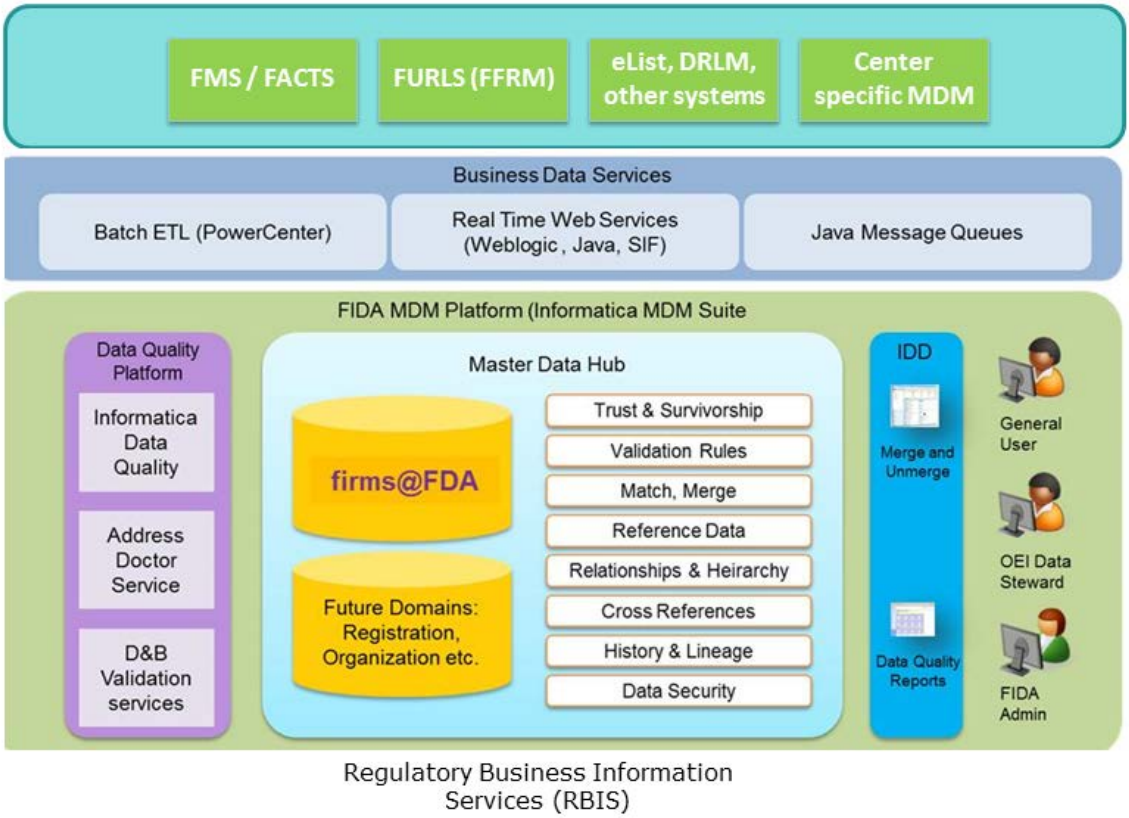

Figure 2. FIDA High Level Logical Architecture

The second major component of RBIS is Business Intelligence and Analytics for data warehousing which includes reporting, dashboards, and mapping capabilities. The main system is Online Reporting Analysis and Decision Support System (ORADSS). ORADSS leverages an industry leading business intelligence tool (SAP Business Objects) for reporting, analysis, and decision support. ORADSS includes a centralized data warehouse repository of ORA data, business intelligence reporting and analysis and ad hoc reporting capabilities. ORADSS integrates regulatory and compliance data from multiple data sources including over 20 functional areas such as Import Shipments and Activities, Work planning, Inspections, Investigations, Firms, Sample and Laboratory Operations, Recalls, Work Accomplishments, Compliance Management, etc. ORADSS also includes data Visualizations and analytics via Tableau Dashboards.

Figure 3 depicts the high-level architecture of the ORADSS data warehouse and the inputs and outputs of the system.

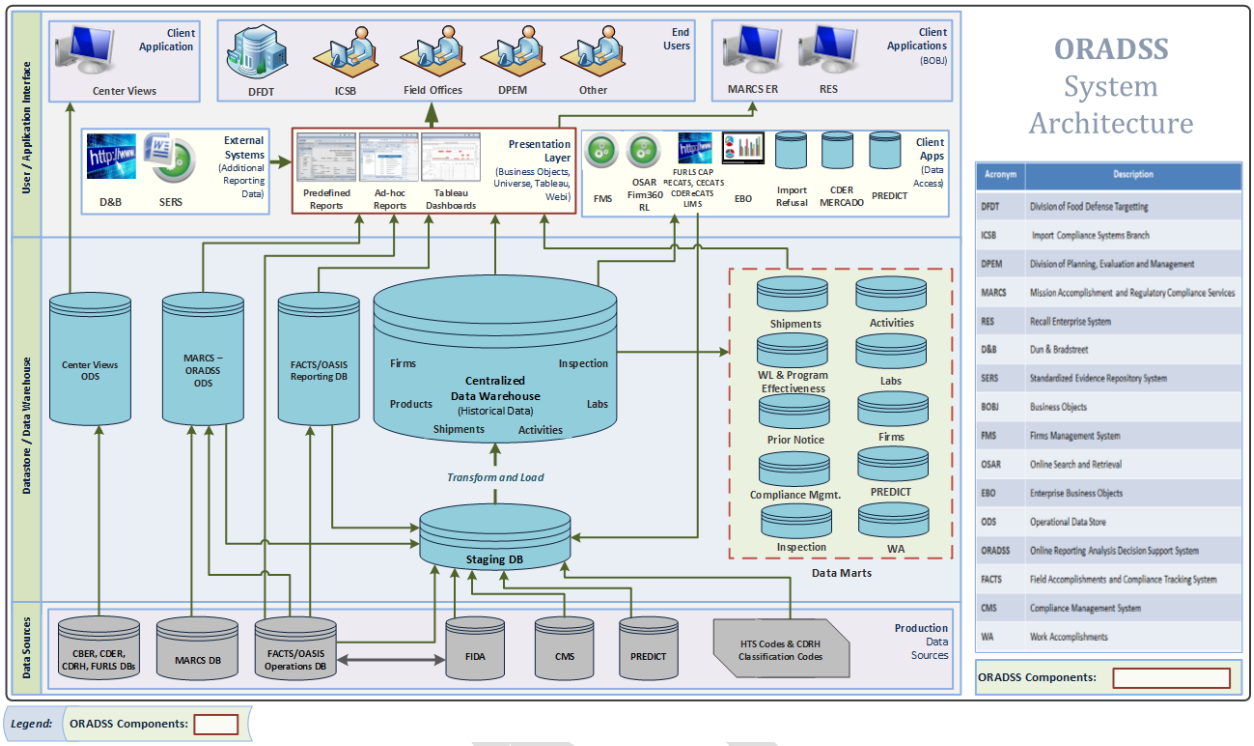

Figure 3. ORADSS High Level Logical Architecture

The third major component of RBIS is Big Data Analytics, which includes Online Search and Retrieval (OSAR)/Firm360, Center Views and Resource Library. OSAR provides Google-like search capabilities to easily view and access structured and unstructured data related to firms, inspections, recalls, sample analyses, compliance, and investigations. OSAR enables searches of documents stored in different repositories and formats (e.g., EIRs, and 483s, Import Alerts, etc.). OSAR uses Google Maps to display firm and inspection locations on an interactive map, with satellite and street views available. Firm360 is a module of OSAR providing users a one-stop-shop of firm details and history information. Firm360 includes merged Firms and provides a comprehensive history of all Firm related activities in one, easy to read location. Available Firm information includes: products, shipments, FSVP information, inspections, samples and lab analysis, citations and corrective action reports, investigations, consumer complaints, recalls, import alerts, compliance cases, work activities, and more. The information is organized in distinct sections and subsections for quick navigation. Firm360 is accessed through a link next to an FEI Number on OSAR.

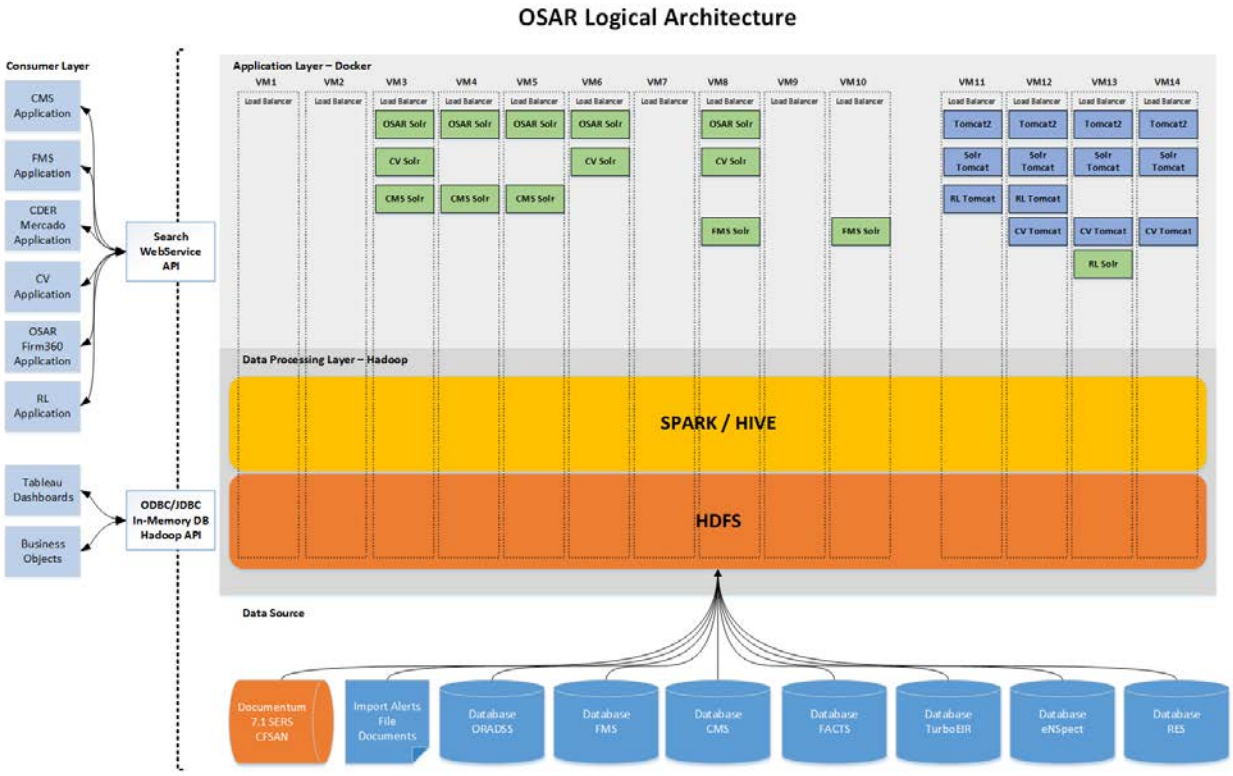

Figure 4. OSAR High Level Logical Architecture

Center Views (CV) is a web-based portal providing 24/7 support to entry reviewers regarding the admissibility decisions of imported products. CV provides a single point of entry and centralized Google-like search capabilities for participating Centers. It allows users to search and view pre-market product application status, firm registration, product listing information, import alerts and bulletins using Center database views from CBER, CDRH, CFSAN and CDER.

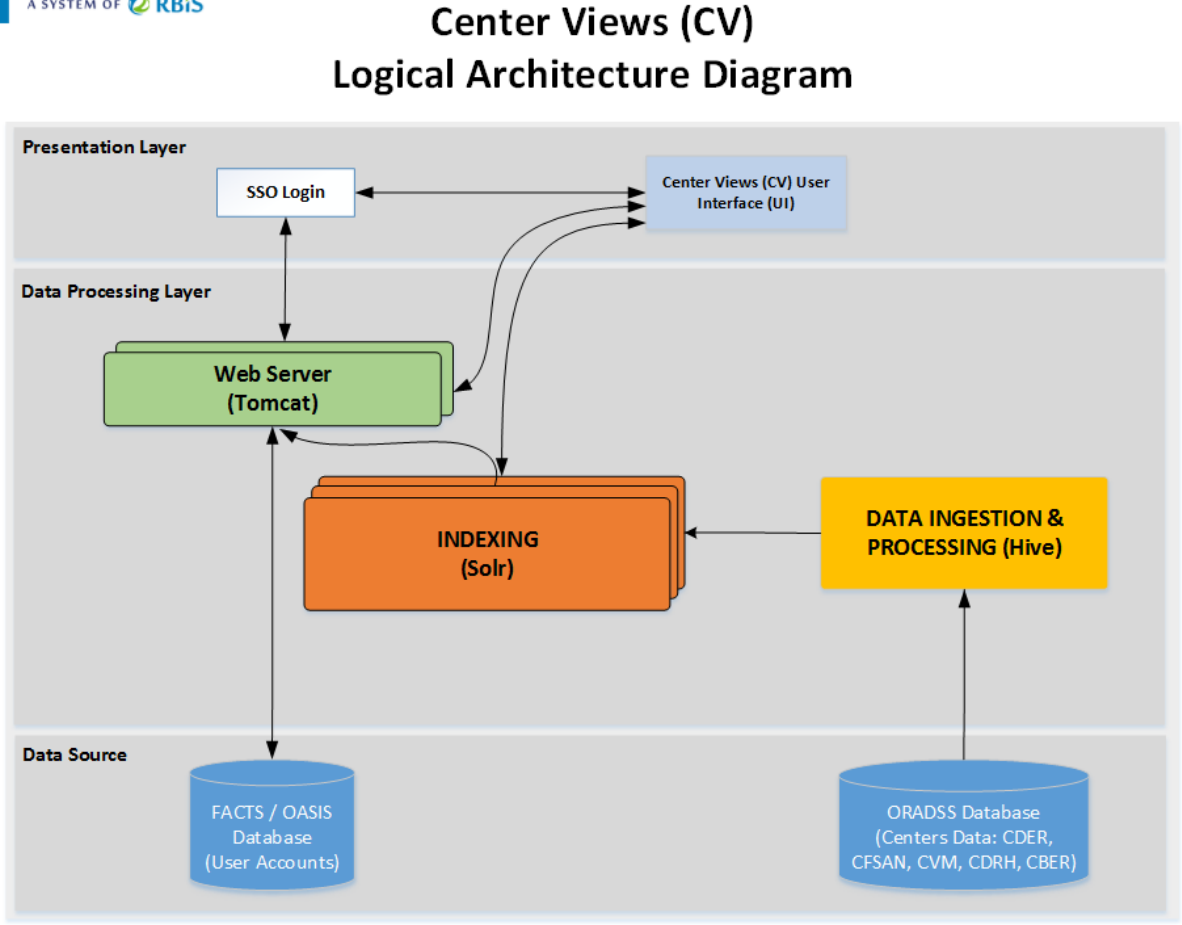

Figure 5. CV High Level Logical Architecture

The Resource Library (RL) is a new tool integrated into the OCAR inspections process providing authorized users with a one stop shop for current, relevant, inspection resources. Currently, RL's focus is to support investigators in preparing for FSMA program inspections. In the future, RL will include additional Centers and program roles. Investigators access RL prior to the start of their inspections to learn more about the regulations, products, industry, and inspectional requirements applicable to their inspection. Examples of resources include: Code of Federal Regulations, Investigations Operations Manuals, Fact Sheets, Inspection and Regulatory Training Videos, and Frequently Asked Questions.

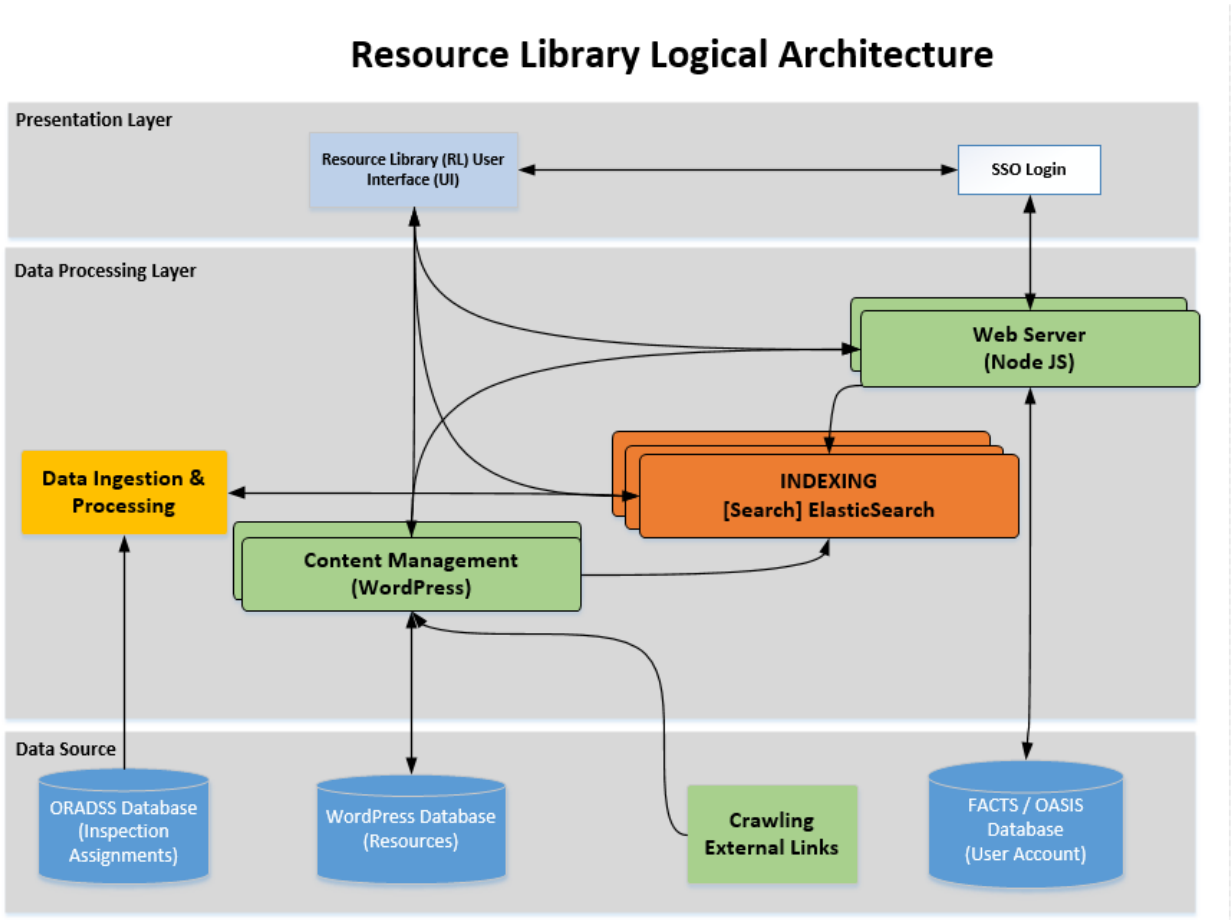

Figure 6. RL High Level Logical Architecture

3. Objectives

The RBIS program is a set of integrated applications that provides data management, data analytics, and reporting functionality to meet the needs of FDA and ORA users (Figures 1-6). The RBIS program seeks the ability to quickly accommodate changes required by the Imports, SIRCE and ALM investments. The ongoing success of the RBIS program is dependent on a program integrator with depth of technical experience in the RBIS technologies and that can also introduce technology innovations to continuously improve the RBIS applications to benefit ORA users.

FDA requires information technology services to support the existing RBIS components and to continue to expand, innovate, and improve program functionality to include real-time data warehousing, integration of data warehousing with document management repositories, master data management, data cleanup, data mining, predictive analysis, social media/big data management, analytics and enterprise search. This includes quickly responding to changes required by FSMA, as well as Imports, SIRCE and ALM in an integrated, coordinated, and flexible fashion so that RBIS may continue to provide the services and data needed. The integration of the RBIS components, specifically the firm master data

management framework, the OSAR Big data platform, and the ORADSS data warehouse, is designed to gain economies of scale for efficient data management in an era of shrinking resources as well as to improve data quality.

4. Purpose and Scope

The scope of this RBIS BPA is to support, maintain, enhance and integrate all RBIS components. The scope includes the following major areas.

1. Program and Project Management of overall RBIS program and its components. The success of RBIS relies directly on the ability of the Contractor to innovate, integrate and coordinate across all the activities and solutions within RBIS, work closely with other FDA contractors on the numerous interfaces, and flexibly accommodate changes due to FDA mandates. The ability of the Contractor to act as a true program integrator will, more than any other factor, determine the success or failure of RBIS.
2. Steady state operations and maintenance (O&M) of current RBIS system components including enhanced or new systems components created as part of DME. Starting with the transition from the incumbent, O&M includes ongoing production, pre-production, test, and development maintenance support, training, and minor enhancements and software upgrades.
3. Development, modernization and enhancement (DME) of RBIS systems components including integration with other FDA systems. This includes further DME of the data warehouse, data marts, and business intelligence solutions, big data and enterprise search & analytics, and master data management. This also includes new development such as COTS implementations. The modernization efforts include infusion of newer technologies in the areas including but not limited to Data Warehouse, Data Quality, Big data, Business Intelligence and Analytical tools, machine learning, predictive analysis, web services and support reporting for handheld devices.

5. Constraints

5.1 *Technical Environment*

The contractor shall continue to support the existing RBIS applications which currently utilize the following technologies but may include additional technologies:

- Master Data Management – Informatica
- Data Management Web Services and other code – Java J2EE, Hibernate, Spring, Quartz Scheduler, Apache Ant, XFire
- Data & Address Cleansing – Informatica Data Quality and AddressDoctor
- Business Intelligence – SAP's BI suite and Tableau Server and desktop clients
- Mapping – ESRI and Google
- Big data & Enterprise Search – Hadoop Ecosystem, Solr, Talend ElasticSearch, Spark
- Enterprise Document Management System - Documentum
- Enterprise Data Integration (batch & realtime) - Informatica PowerCenter
- Distributed application platform and Cluster Management – Docker, RunDeck
- Database - Oracle, SQL server, No SQL DBs (MongoDB), MySQL
- Application Server - Weblogic, Tomcat, Oracle HTTP Server
- Word Press

- Cloudera
- AppDynamics
- Jenkins
- Java J2EE, React.js

The contractor may propose additional software to enhance the RBIS program so long as the Contractor complies with all FDA procedures and standards as outlined in Section 5.

5.2 *FDA Data Centers*

The RBIS applications are primarily hosted at the FDA's data centers. FDA has two primary data centers: the White Oak Data Center (WODC) and the Ashburn Data Center (ADC). WODC is used primarily for development and test environments; while ADC hosts the FDA's pre-production and production environments.

5.3 *FDA Cloud Environment*

FDA is currently leveraging the FDA AWS GovCloud environment. RBIS enhancements will require continued development of shared business systems and services while enabling cloud readiness utilizing evolving technology. It is envisioned that RBIS applications will need to integrate with Cloud-based systems and data sources, in addition to on-premise systems. RBIS Cloud-related tasking could include:

- Migration of Spark/Hadoop servers to AWS
- Development of a roadmap/approach for migration of RBIS applications and services to AWS, including the Implementation of TEST, PreProd, and PROD environments in AWS environments
- Development of fully automated CI/CD pipeline between AWS and ADC in Kubernetes

5.4 *Technical Standards and Guidelines*

The following current standards and guidelines are subject to change as further guidance becomes available, and must be considered in the execution of this contract:

- Health and Human Services (HHS) Enterprise Performance Life Cycle (EPLC) Framework,
- FDA Project Management Process and Templates,
- Food and Drug Administration Investment Life Cycle (ILC),
- IT Infrastructure Library (ITIL).

5.5 *FDA Master Approved Technologies List*

The FDA Master Approved Technology (MAT) List contains a list of approved technologies, including applications (software), infrastructure and peripherals (hardware), and also scientific software and devices. For any technology or software not currently on the MAT list, FDA's Office of Information Management (OIMT) must provide its approval through the "Request IT" process.

Note: Access to the FDA MAT will be provided upon BPA award.

5.6 *Contractor Compliance*

The Contractor shall adhere to all applicable federal information technology and information management laws, regulations, policies and standards at the government-wide, HHS, and FDA levels. At the government-wide level, these include Office of Management and Budget (OMB), National Institute of Standards and Technology (NIST), and General Accounting Office (GAO). These can be primarily found

at or through the Federal CIO Council website at: http://www.cio.gov/. HHS documents are found at: http://www.hhs.gov/oirm/

5.7 *508 Standards Compliance*

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at http://www.section508.gov/. Section 508 Standards were published in the Federal Register on December 21, 2000 (36 CFR Part 1194) and the standards can be access at: http://www.section508.gov/summary-section508-standards.

5.8 *Change Control Procedures*

All changes to software and FDA IT infrastructure shall follow the FDA established change control procedures. These procedures provide a standardized process that ensures efficient and prompt handling of all changes to the software and FDA IT Infrastructure. They will facilitate the efficient and prompt handling of all changes and maintain the proper balance between the need for change and the potential negative impact of changes as well as ensure that traceability and accountability are supported.

5.9 *Release Management Procedures*

All software releases shall follow the FDA established release management procedures.

5.10 *Compatibility with Existing FDA Enterprise Architecture*

Development activities performed under this contract must follow and be compatible with existing FDA Enterprise Architecture standards (Enterprise Architecture at http://www.hhs.gov/ocio).

5.11 *IT Security*

This section ensures the system be compliant with Federal and agency security requirements and support all security related activities including the certification and accreditation process. Project compliance includes:

- HHS Information Security and Privacy Program http://www.hhs.gov/ocio/securityprivacy/index.html
- FISMA http://www.whitehouse.gov/sites/default/files/omb/memoranda/m03-19.pdf
- NIST SP800-53: http://csrc.nist.gov/publications/nistpubs/800-53-Rev3/sp800-53-rev3-final_updated-errata_05-01-2010.pdf
- FDA Security Authorization process, which closely resembles NIST SP800-37: http://csrc.nist.gov/publications/nistpubs/800-37-rev1/sp800-37-rev1-final.pdf

5.12 *Data* Standards *and Guidelines*

FDA intends to fully utilize and comply with existing internal & external data standards where applicable, for its data. For example:

- Use existing standard terminologies/vocabularies such as Dun & Bradstreet (e.g., DUNS); ISO (e.g., 3166-1 Alpha-3 Country Code, ISO IDMP); FDA (e.g., UNII, NDC); Substance Registration System (SRS) etc.
- As appropriate, use the common data exchange format (e.g., XML) in exchanging data among IT component(s).

Additionally, as regulations and standards are implemented to facilitate higher volume of data and better data quality from electronic submissions, FDA will exploit the feasibility of automating and consuming (i.e. acquire, validate, transform, transport, etc.) much of the data directly from input sources, thereby increasing the efficiency and quality of the overall master data environment.

6. Task Areas

The RBIS program is a set of interrelated applications that support ORA's critical regulatory functions. The following sections describe primary areas of support that the Contractor shall provide the RBIS program.

6.1 TRANSITION ACTIVITIES

Transition activities take place to efficiently have the Order requirements transition from the incumbent Contractor to the new or successor Contractor. As tasked, the Contractor may be required to develop transition-in and out plans for orders issued against this BPA contract vehicle based on individual requirements.

6.1.1 *Transition In*

As tasked, the successor Contractor shall provide Transition In support in order to provide an orderly transition from the incumbent Contractor to the successor Contractor. The successor Contractor shall work toward the Government's goal of ensuring minimal disruption to the current system and operational activities. Working with the incumbent Contractor and the Contracting Officer's Representative (COR), the successor Contractor shall develop a plan to take over on-going work from the incumbent Contractor as required in the Orders released under this contract.

6.1.2 *Transition Out*

A smooth and orderly transition-out between the predecessor (incumbent) Contractor, FDA, and successor Contractor is necessary to ensure minimum disruption to vital FDA business. As tasked, the Contractor shall facilitate the transition of contracted RBIS System support related activities and services to the Federal Government or to a follow-on (successor) Contractor at the end of the contract period of performance. The Contractor shall be required to submit and execute a Transition-Out plan to ensure business continuity for the FDA if a new follow-on (successor) Contractor is chosen.

6.2 PROJECT AND PROGRAM MANAGEMENT

The success of the RBIS program relies on the ability of the Contractor to integrate and coordinate across all the activities and solutions within RBIS, work closely with other contractors on the numerous system interfaces, and flexibly accommodate changes required by integrating systems and FSMA and other regulatory mandates. The ability of the Contractor to act as a true program integrator will, more than any other factor, determine the success or failure of RBIS.

The inclusion of project management best practices, careful planning and risk management by the Contractor will support the success of RBIS. The schedule of deliverables requires the delivery of reports,

meetings and draft documentation. The intention of these deliverables is to monitor the Contractor's progress towards delivering final documentation, specifications, and systems of superior quality within schedule and cost parameters. The FDA understands that timely feedback will have to be provided to the Contractor after the review of these deliverables. Additionally, the FDA EPLC process must be followed for all releases. Program and project management are an integral part of the performance of the work defined in this SOW and are directly linked to the successful completion of the other tasks in this SOW.

The Contractor shall perform project management activities, at the task order, program, and individual project level. The detailed requirements for project management are outlined in the individual Orders. All documents referenced, unless otherwise specified, are available in the RBIS Sharepoint repository and will be provided upon award.

6.3 TASK AREA – OPERATIONS AND MAINTENANCE SUPPORT

Operations and Maintenance (O&M) Support for RBIS is comprehensive and includes many different components, each with its own set of specific requirements. The following subsections outline the high-level requirements for the various O&M activities.

6.3.1 *Provide Database Support*

The Contractor shall perform Oracle database administration for the RBIS environments and work with WODC and ADC DBAs to provide RBIS database support. The Contractor shall maintain Oracle user IDs, adjust database sizing, create and assign roles and allocate privileges as necessary. The Contractor shall support creating Oracle "instances" as necessary and support creating and maintaining table space and rollback segments in a logical fashion to optimize performance.

The Contractor shall support all maintenance activities. The Contractor shall document the programs, scripts, and objects that interface with other FDA systems. Standard operating procedures for the DBA shall be updated as necessary to keep them current with each release. For data modeling, the Contractor shall use the FDA standard tool ERWin (www.erwin.com). The Contractor shall support FDA data calls as needed.

The Contractor shall perform similar administration and maintenance activities for non-Oracle RBIS databases, such as MongoDB and My SQL.

6.3.2 *Provide System Administration Support*

The Contractor shall perform system administration functions for RBIS components as directed by the COR. The RBIS Contractor shall operate in accordance with the procedures and policies of the two FDA data centers and provide server monitoring and management support.

The Contractor support for ORADSS shall involve installation and configuration support for Business Intelligence Suite and Tableau COTS tools. This includes managing privileges, running scripts and backend jobs. The contactor shall als support moving reports and builds through the development lifecycle from Development to Production.

Support for Firms master data management involves supporting interfaces with other FDA systems and Dunn and Bradstreet (D&B). This also includes system administration for Informatica Data Quality, AddressDoctor and Master Data Management tools.

Support for OSAR and CV involves support and maintenance for Hadoop, Docker and other big data tools. The contractor shall manage and monitor all Big Data servers, components and jobs in all environments, Development, Test, Pre-Production and Production.

The Contractor shall document and update as necessary activities and procedures including the Standard Operating Procedures (SOPs) for System Administration Support. This documentation shall be kept current with each release. System tuning and monitoring activities shall include monitoring the database and application software for inefficiencies during projected peak times and tuning the database and application software using tools and third-party tools to obtain maximum performance benefits. Additionally, the Contractor shall review existing processes and make recommendations and tune the processes to enhance performance. The Contractor shall conduct testing as necessary and conform to the procedures and policies of the WODC and the ADC.

6.3.3 *Provide Support for New Software*

The Contractor shall evaluate and make recommendations concerning acquiring new software which shall be used to maintain RBIS components and to provide new or improved functionality. The Contractor shall assist FDA in developing estimates regarding expected future expenses and resource requirements. The Contractor shall support the development of prototypes to demonstrate the capabilities and benefits of new tools.

6.3.4 *Provide Support for Business Intelligence Reports*

The Contractor shall provide support for customer requests related to enhancing existing Business Intelligence reports and for developing new reports. The contractor shall support, evaluate, and coordinate the publishing of new BI reports developed by business power users that will benefit the ORADSS user community.

6.3.5 *Provide Support for Tableau dashboards*

The FDA has adopted Tableau as a data visualization and analytics tool. The Contractor shall provide support for migrating selected Business Intelligence reports to Tableau. The contractors shall support minor enhancements to the existing Tableau dashboards. The contractors shall support moving the changes from Development to test, Preproduction and Production environment. The contractor shall support, evaluate, and coordinate the publication of new dashboards developed by business power users that will benefit the ORADSS user community.

6.3.6 *Provide OSAR search and analytics*

The Contractor shall maintain and enhance the OSAR application including components such as Firm 360, services developed for external applications, and infrastructure which includes the Java/Html, ReactJS presentation layer, indexing capabilities, ELT (extract/load/transform) scripts, ElasticSearch search engine, Hadoop framework, Docker, Zookeeper, Tomcat and other OSAR technologies. The Contractor shall be responsible for maintaining the Development, Test, PreProd and Production environments.

6.3.7 *Validate and Audit Data*

The Contractor shall maintain an ongoing data validation process to confirm that the data in the warehouse and data marts and master data management hub accurately represents the data in FDA's source systems.

The Contractor shall develop/maintain validation and audit procedures to allow a comprehensive assessment of the data quality in the warehouse and data marts and monitor for newly introduced errors. Processes shall include systematic review of log reports from the ETL process, queries and reports designed to audit the data, and statistical techniques such as trend analysis. Data validation and audit activities shall be conducted at a frequency which ensures that discrepancies are identified prior to the use of the data in customer reports or queries and that corrections are made before decision analysis is impacted. The FDA Contracting Officer's Representative (COR) shall be informed of all discrepancies and necessary corrections along with an assessment of the impact (or potential impact) of the issue. Data validation activities include the following and may include other activities as needed:

1. Data validation procedures shall be run every night.
2. Validation logs and reports shall be reviewed daily.
3. The Validation Page shall be updated every morning.

The Contractor shall support firm master data management validation processes. The contractor shall utilize data quality tools to help automate the cleansing of existing firm data and the validation of new data in FIDA. FDA's current data quality tool integration is Informatica Master Data Management within RBIS and is a critical component of the data quality initiative to clean up firms data. The contractor shall develop a firm data validation approach to better manage and track the FDA firm data quality. Firm validation shall include at a minimum validation from source systems such as FMS and FURLS. Additionally, firm validation issues shall also be coordinated and communicated as needed to the Firms Data Governance committee.

6.3.8 *Performance and Stress Testing*

The Contractor shall develop performance metrics for all RBIS systems. The metrics shall serve as baseline standards to evaluate performance. The Contractor shall conduct regression, integration, performance, and stress testing for RBIS upon releases of new functionality or significant changes (e.g. a new data mart). The Contractor shall conduct performance and stress testing for upgrades in Oracle database, Business Intelligence, Informatica MDM and Informatica PowerCenter Tools, and Big Data components.

The Contractor shall conduct system performance monitoring and tuning activities for prototype releases, baseline releases, and when changes to the hardware and/or software environment occur such as a new release.

The Contractor shall document performance and stress testing activities, including, but not limited to, benchmarks, test plans, and results. These testing activities shall include sufficient samples of data (such as from the RBIS data warehouse) to simulate realistic system functional utilization and shall show performance measurements with active users scaling up in amounts determined by the FDA.

Performance and stress testing shall be conducted in the Test environment of WODC and in the Pre-Production environment of ADC, depending on which environment is more suitable for particular tests. This involves supporting the provisioning of test databases and test scripts. This testing shall be accomplished in concert with FDA test resources and other contractors at WODC and ADC.

The Contractor shall maintain and development new automated regression and performance test scripts for the RBIS projects.

6.3.9 *Maintenance Releases*

The Contractor shall provide support for releasing additions and modifications to RBIS components (including ORADSS) on a monthly basis or more often as directed by the COR. This support shall include both major and minor releases. This includes deployment planning, deployment support, support for promoting the release to the Pre-Production and Production environments, and associated documentation.

6.3.10 *Help Desk Support*

RBIS provides users with a Tier 2/3 Help Desk to address any issues or questions for each of its component's applications. The Contractor shall provide a Tier 2/3 Help Desk which shall provide support to all RBIS users and assist users in the use of RBIS applications, such as assisting with the use of the Business Objects interface as well as investigate any questions regarding the data or RBIS functionality. The Contractor shall use the FDA ticketing system to support help desk functions. The Contractor shall also coordinate with the Apps Desk which handles Tier 1 activities. Additionally, the Contractor shall actively monitor usage of the application through application auditing.

6.3.11 *Data Migration Support*

RBIS will need to be updated due to data migrations that occur in Imports, SIRCE or ALM. The Contractor shall support data migration associated with Imports, SIRCE, and ALM components as directed by the COR.

6.3.12 *Technology Upgrade*

The Contractor shall monitor and make recommendations concerning software upgrades and replacements. The Contractor shall ensure that all software upgrades are compatible with existing software and shall perform all necessary testing procedures before moving the software to production. Additionally, the Contractor shall modify the existing software and reports as necessary to resolve compatibility issues that occur with software upgrades. This includes making modifications, development and customizations in support of upgrades.

6.3.13 *Task Area – Training*

The Contractor shall provide training and training support in any of the RBIS applications to all FDA RBIS users which could include users from all of the FDA Centers (CBER, CDER, CDRH, CFSAN, CTP, NCTR, ORA) as directed by the COR. RBIS training may be conducted at the DHRD headquarters facility, other FDA site locations including outside of the Washington area. A sample of training tasks includes but is not limited to:

1. Monthly User Group Meetings**:**

   The Contractor shall schedule web-based meetings with users to keep them informed of the changes to RBIS and to provide them with the opportunity to ask questions and provide a learning session. The Contractor shall walk users through step by step instructions in performing Business Intelligence functions in ORADSS such as using the different ORADSS Universes, conducting data visualization and analytics using the Tableau dashboards, demonstrating how to perform basic and advanced searches in OSAR, conducting searches in

CV, and managing resources in Resource Library. The Contractor shall also develop presentation slides for the meetings and record the sessions for users to review afterwards as directed by the COR.

2. On Line Training:

   The Contractor shall create, update, and enhance online training sessions to guide the users through the different RBIS application functions within FIDA, ORADSS, OSAR, RL and CV. These sessions shall provide the users step by step guidance through the process. These sessions shall be recorded sessions and are not interactive sessions with live users.

3. Class Room Training:

   The Contractor shall assist the ORA DHRD scheduled training sessions and the FDA Centers in providing class room training for the RBIS ad hoc customers. The Contractor shall assist with room set up prior to the training class which may involve the installation of software and granting of privileges for the students. The Contractor shall maintain a Training instance. The Contractor shall also be available in person and/or remotely during the training class to answer questions. The Contractor may also occasionally be called upon to perform portions of the training or assist with the training and troubleshoot any problems that may occur. The Contractor shall assist DHRD in developing training materials.

6.4 TASK AREA – DEVELOPMENT MODERNIZATION AND ENHANCEMENT

The Contractor shall perform activities to further develop, modernize, and/or enhance RBIS components that result in deployed and implemented functionality. This includes new development and the introduction and/or use of customized Commercial off the Shelf (COTS) or Open Source products implemented according to FDA Standards (see Section 5).

As DME tasks are implemented and become production systems, they are "rolled" into the O&M task.

6.4.1 *Concept Development/Business Analysis*

The Contractor shall support, evaluate and document recommended improvements to existing processes and produce best practice documentation for RBIS data standardization, workflow process enhancements and migration of its support tools. Recommendations could focus on areas such as data standardization strategy, business analysis, system architecture and infrastructure framework improvements or business and technology roadmaps to align ORA's solution with the enterprise FDA data standardization vision.

6.4.2 *Master Data Management Governance and Data Stewardship*

The Contractor shall provide data investigation and analysis support for the ongoing data quality initiatives as part of FIDA. Data investigation and support involves determining how FIDA is processing data and if any changes to the matching rules are required (e.g. rules tuning). Upon investigation and analysis, the data stewards must work with the business owners to determine if changes are required and if necessary, consult with the ORA Data Governance board for additional guidance. Support includes facilitating and preparing materials for the bi-weekly ORA Data Governance meetings.

6.4.3 *Content Management Governance*

The Contractor shall develop governance procedures for the application content and data harmonization. Content Management Governance can apply to documents, systems that store or manage them, and artifacts or organizations used to manage the documents. "Artifacts" refers to items

such as definitions, metadata spreadsheets, graphical views of the taxonomy, and other supporting items such as search system thesauri.

6.4.4 *Report Development Support*

The Contractor shall provide ongoing Report Development Support to ORADSS customers using Business Intelligence and Tableau. Tasks could include the following activities:

1. Assist users with report development.
2. Develop new Business Intelligence and Tableau Dashboards and modify any existing reports and dashboards as directed by the COR.
3. Develop reports for emergency requests such as Congressional Inquiries and Freedom of Information requests. The Contractor shall give these requests priority.
4. Tune reports and queries as needed.

6.4.5 *Center and External Integration*

The objective of Center Views (CV) is to provide data search functionality to Import Operations personnel so that they can review FDA Center data from CBER, CDER, CDRH, CFSAN, and CVM. Center Views provides the reviewer with a method to search Center items against the Center Process Registration System to verify the product's acceptability, to determine whether more information will be needed prior to approval, or to flag items for inspections or other type of actions. Additionally, it provides the means to conduct a search of Import Alerts, which provides detailed product, country, manufacturer information, and other data that must be considered prior to approval of any import. The contractor shall modify CV to provide the users with the convenience of having access to Center data on one screen with a single logon. With CV, the user can jump from one Center's data to another without losing the previous Center data search results. The search results can be sorted in any field order that the user so desires.

6.4.6 *Data Warehouse, Data Marts, and Universes*

The Contractor shall develop new data marts, enhance existing data marts and the data warehouse, and develop future phases of existing data marts in order to provide customers with user friendly access to FDA data. The Contractor shall develop new and modify existing ETL processes to create data marts and make modifications to the data warehouse. This includes enhancements to the Data Warehouse, existing Data Marts and creating new Data Marts.

6.4.7 *Near Real-Time Data Warehousing*

The Contractor shall develop near real-time (at least two data refreshes within a 24-hour time period) data availability to support reporting and analysis. It shall include 24 X 7 operational reporting to improve access to regulatory data for supporting those operations in which time sensitive actionable data is required for quick turnaround of decision making. It will reduce the reporting load on operational source systems allowing for enhanced transactional processing and increase the effectiveness of FDA business operations by speeding up the availability of relevant and critical data through ORADSS.

6.4.8 *Enhancements to Firm Master Data Management*

With the initial rollout of Informatica Master Data Management to replace FDA's previous firms data clean up system, Firms Master List Services (FMLS), FDA has a significantly improved set of tools to manage, maintain, and cleanse the firm's data inventory. The next phase of the Firms MDM effort shall focus on several key areas detailed in the following sections.

6.4.8.1 *Firm Data Quality*

The Contractor shall monitor and update the match and survivorship rules of the current on-demand Firms data profiling processes on an ongoing basis to ensure data quality remains within acceptable limits and to recognize problems and react to them before the quality of the Firms data declines. Monitoring will help identify trends in Firms data quality, provide alerts of violations in established data quality and business rules, and detect when firms data exceeds pre-set limits.

The Contractor shall develop a firm data quality program to monitor and track issues with FDA regulatory firm data. The validation program should use a combination of reports, dashboards and queries to assess and communicate firm data quality to FDA stakeholders.

6.4.8.2 *Supports FDA Dun and Bradstreet Initiatives*

RBIS shall integrate Dun and Bradstreet information, including DUNS numbers to support firm matching and survivorship.

6.4.8.3 *Outreach Program to Perform Data Clean Up in Agency Systems*

FDA has multiple systems that use Firms and Product data. The Contractor shall reach out to the Centers to leverage the RBIS Informatica Master Data Management COTS tool to support the improvement of the data integrity and quality of product data. This shall involve establishing an initial inventory of data from the various Center datasets and establishing data validation and standardization methods in order to ensure data integrity. Additionally, the Contractor shall support implementation for any enhancements to RBIS firm components in FIDA.

6.4.8.4 *Integration with other ORA systems*

FIDA is the central repository of firm data and as a result the Contractor shall support integration of FIDA with other FDA systems include FMS, ACE/IWS, Prior Notice Manager, and Center registration systems.

For example, Firm Management Services (FMS) shall need the support of RBIS to improve and maintain Firms data quality in Imports and SIRCE. Firm address validation and match services shall be provided to FMS to help verify domestic and foreign firm addresses and identify potential duplicate firms before they are added to the system. Additionally, as FMS enhancements are released, the Contractor shall be required to support any corresponding changes to FIDA.

6.4.8.5 *Incorporate Center Registration Data into Firm MDM*

The Contractor shall support the enhancement of FIDA to include Center Registration information. For example, enhancements could include (but are not limited to) adding Center Registration data from Center systems such as FURLS Device Registration and Listing Module (DRLM) and Food Facility Registration Module (FFRM) for medical device registrations and foods, respectively. The Contractor shall coordinate with Center staff and subject matter experts to develop the necessary integrations between the Center systems and the firms MDM hub.

6.4.9 ***Support Enterprise Search***

The Contractor shall support the continued enhancement of the RBIS enterprise search application, ORA Online Search and Retrieval (OSAR), which includes the Firm360 component. OSAR provides the ability to index and search on a variety of FDA databases, documents, and web sites to return structured and unstructured data. The Contractor shall continue to expand on the OSAR search capabilities and the Big Data platform by incorporating additional FDA critical information such as consumer complaints, adverse events, import alerts and import bulletins, compliance cases and work activities, social media, webpages, and SharePoint documents. The Contractor shall develop scripts for performing ELT (extract/load/transform) to load data from multiple sources into Hadoop HDFS. The Contractor shall

evaluate new tools and recommend strategies and techniques for analytics and predictive analysis using big data in support of FDA mission.

The Contractor shall develop and enhance new indexes and provide API services to support searches being conducted on Centers systems and Imports, SIRCE and ALM applications as directed by the COR.

6.4.10 *Data Mining /Advanced and Predictive Analysis*

The use of machine learning, data mining and predictive analysis solutions applied to ORADSS Data Warehouse data shall provide answers to specific business issues related to data on past, present, and projected future actions. Advanced analytics shall enable proactive risk management including risk-based sampling and risk-based inspection programs, serving as a guide for refining key decision making processes. By deploying advanced analytics, specific FDA goals relating to process improvements and advantages can be achieved.

Using ORADSS domestic, imports, laboratory, compliance, and Center data, data mining and advanced analytic solutions, the Contractor shall develop procedures and methods which allow FDA to effectively target regulatory resources to problem areas. Advanced data analysis techniques could include confirmatory data analysis that shall help support expert hypotheses through analytical rigor and a complementary approach and exploratory analysis of large data sets which shall also help to identify previously unknown trends. When used in combination, these two techniques provide a powerful mechanism for surveillance, support the detection of risks and threats in supporting infrastructures, contribute to preparedness planning, and will be instrumental in prioritization of both proactive and reactive efforts to resource allocation. Such risk-detection techniques shall help in identifying firm, product, and process risks which will be immensely useful in risk-based inspection, sampling, and examination applications. Advanced analytic methods may also assist in ensuring regulatory compliance and assess the risk of FDA regulated firms.

6.4.11 *Documentum Integration*

As part of the Big Data platform, the Contractor shall provide integration of documents and other types of unstructured data from various sources such as Documentum, District file shares, social media and other big-data sources that could be used to provide valuable information and analytics to support FDA's mission. The Contractor shall evaluate and recommend tools for social media analytics to integrate with RBIS Hadoop Data Lake. The Contractor shall develop requirements and design for integrating with the FDA Common Electronic Document Room (cEDR).

6.4.12 *Web Services*

The contractor shall develop technologies such as Web Services for RBIS applications. Web services could include those that other applications can call to seamlessly pull ORADSS canned reports directly into their application without users having to log into the ORADSS system.

The Contractor shall develop web services in support of external applications by providing seamlessly ORADSS data warehouse data. The Contractor shall develop other web services for Big Data. Big Data web services shall include the development of services to leverage OSAR and Firm360 capabilities.

6.4.13 *Data Discovery and Visualization Capabilities*

The Contractor shall develop Data Discovery and Visualization Capabilities which could include but are not limited to Executive Decision Support Dashboards. For example, the Contractor could develop

Executive Decision Support Dashboards for Compliance which could automatically alert users when thresholds are surpassed, and action needs to be taken. The dashboards and reports shall be designed to assist managers with their day to day duties, as well as to provide alerts when thresholds have been met.

Executive/Decision Support Dashboards shall provide FDA executives and managers with metrics to monitor their work plans and track their performance goals. Dashboards shall be comprised of metrics that are tailored to individuals in the organization by role and organizational level. Dashboard capabilities shall support better planning of inspections, import review and screening processes, and other regulatory compliance measures. Dashboards may leverage real-time data warehousing capability to generate dashboard reports to alert FDA executives and managers of potential issues and threats.

Additionally, the Contractor shall develop dashboards and reports that may include information on data quality, such as the overall state of FDA firm data, trends of duplicates, gray area firms, and other data quality characteristics over time. Dashboards and reports shall assist in reporting and in providing metrics that yield business intelligence about firm data to help tune the FDA applications and processes and provide insight into ongoing data quality efforts. Dashboards may be developed using Tableau.

6.4.14 *Imports and SIRCE Reengineering*

The ORA Investments Imports and SIRCE are being reengineered and RBIS requires integration with these systems that support ORA. Changes to the RBIS components may be required in support of the Imports and SIRCE re-engineering effort. Imports and SIRCE components also access firm data residing within RBIS via FMS. One of the enhancements to meet ORA's functional and architectural requirements shall be for RBIS to provide standard services for firm information for all Imports and SIRCE applications. RBIS shall also support the FDA's imports strategic plans to improve data quality, integrate and consolidate imports-related systems and processes, and increase ability to share information with other agencies.

6.4.15 *Geospatial Enhancements*

The ability to locate and map firms has become important in the day to day operations of the FDA, as well as the agency's ability to respond to emergencies. It has become imperative that the agency be able to identify firms that are in the paths of disasters such as hurricanes and tsunamis in the United States and beyond our borders in nations around the world. As a result, there is an increasing need to provide the latitude and longitude for all firms, domestic and foreign, in order to determine a more precise location.

The Contractor shall evaluate current and emerging geospatial technologies to enhance geospatial functionality in the RBIS applications including ORADSS and OSAR. The selected technology shall improve the latitude and longitude coordinates for foreign firms. The data shall include the ability to report on details of site characteristics in the context of geographic boundaries, demographics, and other sites or features, if available. The contractor shall integrate geospatial information with FMS.

6.4.16 *Enhancements in support of Food Safety Modernization Act (FMSA)*

The Contractor shall support necessary enhancements to the RBIS applications as required by the Food Safety Modernization Act (FSMA). FSMA programs include but are not limited to the following: Third

Party Program, Foreign Supply Verification Program, Volunteer Qualified Importer Program, Importer Certification, Laboratory Accreditation, System Recognition, Preventive Controls, and Produce Safety.

6.4.17 *Enhancements to support Mobile Devices*

The Contractor shall provide capabilities to develop mobile applications for existing RBIS applications. RBIS mobile applications shall be designed to integrate with transactional systems within Imports, SIRCE and ALM in support of field operations. Mobile applications developed could include phones and/or tablets. The Contractor shall work with FDA to identify potential needs and develop prototypes and mock ups as needed.

7. Period of Performance

The period of performance will be based on period of 12 months from the effective date of the BPA plus 4 one-year option periods.

Each Order will specify its individual period of performance.

This BPA cannot extend beyond the term, inclusive of exercised options, of the underlying FSS contract.

8. Place of Performance

The majority of the work shall be performed both offsite at the Contractor's facility as well as the government's White Flint North Office. Additionally, the Contractor shall attend meetings held at various FDA locations within the Metro DC commuting area.

9. Personnel

Key Personnel will be identified in the individual Orders. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer Representative. The Government may modify the BPA to add or delete key personnel at the request of the Contractor or Government.

The Contractor shall ensure that all Contractor personnel are adequately trained, possess credentials appropriate to their labor categories, and are otherwise fully qualified to provide the high level of support required by this BPA. FDA expectations are that the Contractor shall have the ability to effectively service this BPA with experienced, knowledgeable, professional and capable personnel who have successfully performed similar tasks as those described in this document. The Contractor shall provide adequate supporting documentation regarding personnel qualifications to the COR for review in the form of resumes, curricula vitae, or other similar documentation that demonstrates requisite training and experience.

10. Government Furnished Information/Equipment (GFI/GFE)

GFI or GFE will be determined based on requirements defined in the each Order.

11. Deliverables

Deliverables shall be defined at the Order level. Deliverables are scalable relative to the risk, size and complexity of the project. The Contractor shall work with the Government to determine the appropriate level of deliverables and milestones to ensure a successful outcome. Furthermore, the FDA may inspect deliverables at any time, including in draft format. Therefore, the Contractor shall make draft and final deliverables available in the appropriate FDA document repositories.

The Contractor shall deliver the deliverables in electronic format unless otherwise stated. This includes formats in the MS Suite such as Microsoft Office (Word, Excel), MS Visio, MS Project, Adobe Acrobat, and XML or other electronic format as prescribed by the COR (such as source code).

12. Inspection and Acceptance

Unless otherwise expressed in the individual Tasks, within 10 business days of receipt of an official deliverable, the COR and/or designee will review the deliverable and suggest any changes and/or accept or reject the deliverable. In the event the Government rejects any deliverable, the COR shall notify the Contractor in writing explaining the specific reason(s) for the rejection. If the Government suggests changes, or rejects, the Contractor shall resubmit the revised deliverable within five (5) business days after receiving the Government's input.

Deliverables shall be produced and submitted for approval according to the Project Plan. Each deliverable shall have a stated criterion by which the successful completion shall be approved, and final approvals will be at the discretion of the COR.

Acceptance will be based upon overall completeness of the required task, accuracy and reliability of the deliverable and review/approval by the COR. Accuracy, reliability and completeness will be determined based on the ability of the deliverable to meet its intended goal in a clear and concise manner. The COR will provide acceptance in writing to the Contractor.

The Contractor shall propose a form to be used to submit deliverables and receive COR approval in a prescribed time interval.

13. Travel

All Travel will be managed at the Task levels and in accordance with the requirements set forth within the Task. Travel costs from outside the Washington DC metro and surrounding area shall be in accordance with the Federal Travel Regulations (FTR) and FAR 31.205-46(a)(2). Requirements for travel will be provided in each individual Tasks.

Performance under this BPA may require travel by Contractor personnel. Any required travel by the Contractor shall be conducted by the direction of the Government, and must have written approval by the COR prior to booking and conducting travel. Costs associated with approved travel shall be reimbursed at actual cost, or by established Government per diems, whichever is less. Travel costs exceeding rates and per diems established under Federal Travel Regulations (FTR) are prohibited from reimbursement without written Contracting Officer approval prior to the associated travel being conducted. All travel shall be conducted in strict accordance with FAR 31.205-46, Travel Costs and FTR.

Before Conducting Travel

Prior to booking or conducting Government-direct travel, the Contractor shall provide a written request for travel to the COR and CO. The Contractor's request for travel shall be in writing and contain the dates, locations and estimated costs of the travel. The Contractor shall then coordinate specific travel arrangements with the COR and must obtain advance, written COR approval for the travel to be conducted. The Contractor shall, to the maximum extent practicable, minimize overall travel costs by taking advantage of discounted airfare rates and other travel-related expenses available through advance purchase.

I. Additional Travel Requirements and Limitations

Air and Rail transportation shall be reserved for and conducted under economy class only, unless written approval is provided by the Contracting Officer prior to the travel reservation. Vehicle rentals are authorized only when travel is conducted utilizing air transportation, unless written approval is obtained by the Contracting Officer prior to reserving a rental vehicle. Vehicle rentals for Contractor personnel are limited to one car for every four (4) persons for travel to one location. Vehicle rentals reserved and utilized must be the least expensive class of vehicle available at the time of reservation or utilization. Vehicle rentals that are not categorized as economy class or compact class will not be reimbursed. If economy class or compact class vehicles are not available at the time of reservation, documented proof must be provided to the Contracting Officer and approval must be obtained by the Contracting Officer prior to reserving a rental vehicle.

If travel is required, the Contractor is responsible for making all needed arrangements for Contractor's personnel.

II. Travel Changes and Cancellations

Prior to changing and/or cancelling any travel that will incur cancellation fees, the Contractor shall notify the COR in writing of the total amount of the fees associated with Government-directed travel changes and/or cancellations. The Contractor shall consider and purchase reimbursable tickets when it is more beneficial to the Government.

III. Local Travel

Travel performed for personal convenience or daily travel to and from work at the Contractor's facility or local Government facility (i.e., designated work site) within the Washington DC metro region shall not be reimbursed hereunder. "Local" is defined under this term as the travel destination located within the Washington DC metro region.