Statement of Work (SOW)

OBIEE Compactible for Geo Spatial Data

Software License and Support

Hardware & Software License and Support

Mar 18, 2014

1. Background

In support of the Food and Drug Administration's (FDA) mission to "Promote Public Health by Advancing the Safety and Effectiveness of Medical Products", the Center for Drug Evaluation and Research (CDER) is charged with overseeing the review and approval of human drug products to ensure that they are safe, effective, meet established quality standards, and are available to patients according for their intended use. Accordingly, CDER has defined and published the following regulatory business processes as part of its operating model in the FDA CDER Strategic Plan 2012-2017:

- Oversight of new drug development and review of drug marketing applications
- Oversight of post-market drug safety to ensure safe use of approved medicines

The above regulatory business processes require that CDER has effective means of receiving, storing, disseminating, reviewing, reporting, analyzing, and retaining regulatory data. Presently, CDER uses unique IT systems, reporting tools, and business processes that provide FDA with information from various sources associated with the respective business areas. Data in transactional processing databases is not stored, organized, and presented in a way that facilitates ease of use, consistency, and performance.

In order to enhance the overall capability to approve safe and effective medical products in CDER, a core set of reporting and analytical capabilities is needed. The need for this core set of reporting and analytical capabilities come on the heels of new legislation enacted within the past year, including the Prescription Drug User Fee Act V, FDA Safety and Innovation Act (FDASIA), and Generic Drug User Fee Act, create a renewed need to provide business users and management with capabilities to analyze, monitor and report on performance on this new set of legislation.

CDER has already acquired a commercial off-the-shelf (COTS) business intelligence (BI) tool to meet their flexible querying, reporting, and analysis capabilities with a greater degree of self service.

2. Objective

FDA already established a consolidated data repository across multiple data sources powered by OBIEE Foundation Suite BI tool to perform data analysis and reporting. The objective is to acquire and integrate the Geo spatial digital map database into CDER's analytics platform. The Geo spatial data will reside in the Oracle database and provide the OBIEE tool, the capability to pin point an address related to FDA business functions on a map.

This feature will benefit end users by providing them a capability to view information on a map and then be able to perform analytics using standard OBIEE tool capability.

3. Requirement

The CDER has needs to meet the analytical requirements of wide array of CDER business domains including but not limited to Drug Safety, Drug Quality, Drug Regulatory review, Business Management and Operations. The focus on pharmaceutical quality platform is to geo-map the facilities that manufacture drug products in case of issues, to ensure the stability and quality of supply chains. Current analytics platform is deficient with regard to visualizations and OBIEE Compactible for Geo Spatial Data provides one of best map databases which are very comprehensive due to their comprehensive market research. This is a COTS product, a modular piece of software that we are going to plug into an existing CDER system. CDER has specific requirements to enforce data security the hardware/software being proposed at a minimum shall meet the following requirements listed below:

1) Provide navigable footprint - Data is available globally
2) Accurate data - Provide data that is superior with positional accuracy
3) Security - Data is hosted within FDA database which leads to, better performance for user requests and high security control
4) Geocoding and display - Provide digital base map layers with display and geocoding capability
5) Update options – Including quarterly, semi-annual or annual updates
6) Data available at various levels including by county, province, state or entire country
7) Data available at granular levels including information related to streets, addresses, zip or post codes, city locations, highways, state boundaries etc
8) Compatible with Oracle Geo Spatial database
9) Spatial data should support special spatial data type in Oracle called SDO_GEOMETRY

10) OBIEE BI interoperability to extend the tools map capabilities

11) **Compliance with FDA Security Requirements** – The OBIEE Compactible for Geo Spatial Data and BI Software tool shall comply with relevant National Institute of Standards and Technology (NIST) Security guidelines, and Federal Information Processing Standards (FIPS). Security guidelines and FIPS publications can be found at the URLs below:

NIST 800-53 publications can be found at: http://csrc.nist.gov/publications/PubsSPs.html

FIPS publications can be found at : http://csrc.nist.gov/publications/PubsFIPS.html

4. Deliverables

Vendor shall deliver the following to the Government:

- Hardware and required components
- Software and licensing key, Software and User Manuals in a digital copy provided on a CD or DVD:

	Product Name or Similar	Licensing Model
1	OBIEE Compactible Global data for Geo Spatial	Support existing OBIEE Unlimited licensing model for CDER

Deliverables are delivered to the following address:

U.S Food and Drug Administration
Center for Drug Evaluation and Research / Office of Business Informatics
10903 New Hampshire Avenue
Silver Spring, MD 20993

Schedule: Delivery shall be 30 days after contract award.

Vendor is **not** responsible for installation of the software. FDA staff will install the software.

Training: No training is required with the purchase of this software

5. Inspection and Acceptance Criteria

Working media: FDA will load the software and licensing to verify that the media is functioning properly. The Government shall have 20 working days to inspect and verify that the software is operational, functional and compatible with FDA servers and software post-delivery activities.

6. Points of Contacts:COR: The COR assigned to this contract is responsible for maintaining the contract record, timely receiving of receipts, and for communicating with the Project Officer

and Contracting Officer/Specialist to ensure the vendor is meeting the requirements of the contract.

The COR for this contract is **TBD**

52.211-6 Brand Name or Equal (Aug 1999)

FDA conducted preliminary research and it appears to FDA that OBIEE Compatible In-Memory hardware seems to meet all of the requirements outlined in the SOW. However, if there is a similar hardware/software that can meet the requirements, vendors can propose for Government's review and consideration.

(a) If an item in this solicitation is identified as "brand name or equal," the purchase description reflects the characteristics and level of quality that will satisfy the Government's needs. The salient physical, functional, or performance characteristics that "equal" products must meet are specified in the solicitation.

(b) To be considered for award, offers of "equal" products, including "equal" products of the brand name manufacturer, must—

(1) Meet the salient physical, functional, or performance characteristic specified in this solicitation;

(2) Clearly identify the item by—

(i) Brand name, if any; and

(ii) Make or model number;

(3) Include descriptive literature such as illustrations, drawings, or a clear reference to previously furnished descriptive data or information available to the Contracting Officer; and

(4) Clearly describe any modification the offeror plans to make in a product to make it conform to the solicitation requirements. Mark any descriptive material to clearly show the modification.

(c) The Contracting Officer will evaluate "equal" products on the basis of information furnished by the offeror or identified in the offer and reasonably available to the Contracting Officer. The Contracting Officer is not responsible for locating or obtaining any information not identified in the offer.

(d) Unless the offeror clearly indicates in its offer that the product being offered is an "equal" product, the offeror shall provide the brand name product referenced in the solicitation.

(End of provision)