CASE STUDY

DEPARTMENT OF HEALTH AND HUMAN SERVICES/FOOD AND DRUG ADMINISTRATION

CDER Electronic Submissions Processing (ESP) Program Support.

SCOPE OF WORK

Iyka supported FDA's Electronic Submissions Program (ESP), which receives and routes for processing applications for Drug and Biologic product approvals. Implement standard processes for Regulated Product Submission (RPS), a Health Level Seven (HL7) standard. Define requirements by verifying, validating, and updating requirements for a COTS submission validation tool, incorporating the HL7 RPS Release 2 requirements. Integrated, tested, and deployed multiple versions (2010 & 2014) of the COTS Global Submit Validation tool (which enables e-submission validation and viewing), the underlying Oracle Database, and the Reviewer Tool support of greater than 3000 FDA users. Rewrote significant components of the ASR integration code, eliminating 100% of the existing system hangs and reducing monthly trouble tickets by 90%. Perform O&M (including many system enhancements) as and1, 2, and 3 "Help Desk" support for users. Support the submission, processing, and evaluation of over 500,000 re-submissions annually.

DESCRIPTION OF WORK

Drug and Biologic application related documents can be submitted by sponsors in an electronic format as eSubmissions through FDA's Electronic Systems Gateway (ESG). Up to 900 eSubmissions are received daily by the FDA Center for Drug Evaluation and Research (CDER) and the Center of Biologics Evaluation and Research (CBER). The Electronic Submission Program (ESP was created in 2010 to provide support for the receipt, processing, and review of Drug and Biologic electronic submissions that ard by CDER and CBER. Iyka team of Application Developers and Business Analysts provide the Electronic Submissions Program full systems development life cycle (SDLC) support activities, O&M as well as testing, user acceptance, implementation, and support of COTS e-submission validation and viewer tools. The Iyka team recently completed a technology refresh and continues making further enhancements to the Automated Submission Receipt (ASR) System that conducts the initial validation of electronic submissions received through FDA's Electronic System Gateway (ESG) and extracts metadata to pass to an FDA critical submission tracking system and their COTS validation tool. The application was written in .NET and deployed on the IIS-Windows server. It integrates multiple technologies including iText and Oracle 11g.

RELEVANCE OF THE WORK PERFORMED

Main services provided for this project fall in the NAICS code of 541511, Custom programming services. The Iyka Team was responsible for 3 components: their Validation Tool, their Oracle Database upgrade, and the Reviewer Tool. Iyka provided 5 IT resources and managed the contract and project.

ABOUT IYKA

Headquartered in Greater Chicago, Iyka is a multiple national and international award winning strategic data management company. Iyka brings innovative products, Applications Development, and IT staff augmentation services that simplify technology and technology processes to serve commercial, educational, and government clients.

Iyka Enterprises, Inc. (Iyka) is an MBE / WBE / DBE / BEP / WOSB / 8(a) certified business that has served over 100 global public sector and private sector clients since 2000. Iyka holds multiple SLED, Fed, and Commercial professional IT services Master Contracts, IDIQ contracts, and GWACs.

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