Sciformix Accelerator Methodology Delivers Validated Oracle Argus Cloud in Record Time

Client

A global pharmaceutical company that is actively engaged in R&D and offers prescription drugs across a wide range of therapeutic areas including Oncology, Gastroenterology, Antidiabetic, Antibiotics, Cardiovascular, Pain Management, and Gynecology.

Client Situation

Due to growth through acquisitions, the company had multiple subsidiaries, each with safety data in disparate systems. This made it difficult to access and view their data, make informed decisions, and manage reporting to regulatory authorities. In addition, the safety data was being managed at different levels of effectiveness, which resulted in a lack of control. Given this situation, the client sought to implement a consistent, validated, and secure best-of-breed safety solution.

The client’s immediate need was to integrate and implement individual safety databases for two of their subsidiaries on the Oracle Argus platform. The project was complex, as safety data from both subsidiaries had to be hosted on dedicated, but different, Argus databases. All activities had to be performed in duplicate for both sites, each with separate development, pre-production, and production environments.

Finally, the client proposed a very stringent timeline of 38 calendar days to complete the project, as their contracts were ending with their current providers.
Solution

Given the significant project requirements and impact to the business, the Sciformix Accelerator Methodology was proposed and implemented. This ensured that all project timelines would be met and a robust, validated, and secure solution would be delivered. This methodology consisted of three main components:

- **Structured Program/Project Oversight and Management** consisting of formal processes that facilitate effective communication among integrated cross-functional teams, effectively manage issues, and ensure quality at every stage of the project
- **Comprehensive IT Global Quality Management System (QMS)** designed in accordance with ISO27001:2013, ISO9001:2008, ITIL V3, GAMP, ICH, and other global best practices to conform to the highest levels of quality, regulatory and compliance standards
- **Virtualization Methodology and Standardized Validation** designed to speed up project timelines and ensure comprehensive quality across both the application and operating environments

**Structured Program/Project Oversight and Management**

Sciformix responded to the client’s request by quickly assembling a dedicated team of technical and business experts who developed a plan to implement the system along with specifying staffing and the level of effort required to meet the required timeline. The project team comprised Argus functional and technical experts, IT infrastructure specialists, validation consultants, and a project manager. In addition, a functional QA specialist was assigned to ensure quality at every stage of the project.

The Sciformix and client teams coordinated seamlessly to ensure that every aspect of the project was planned and executed effectively and on-time. The project manager conducted bi-weekly meetings with the client’s pharmacovigilance business team (Sciformix) and weekly meetings with the client’s oversight team during the project life cycle. This ensured that all user requirements were captured and workshops/demonstrations were conducted to confirm the requirements, propose the technical solution, and create the Argus configuration. While the teams worked together as a whole, each function was responsible for overseeing and executing their various project activities as detailed below:

- CSV-ISC team: Validation plan and all project validation documentation
- Argus technical team: Implementation system architecture plan
- Argus functional experts: Application configuration, User Acceptance Test (UAT) plan and scripts
- IT infrastructure team: Validated infrastructure and computing environments
- Customer pharmacovigilance business team: Executed UAT scripts
- Program Manager: System handover documents and System Release Notes

In addition, a formal Issues Management program was implemented to facilitate effective communication and ensure seamless resolution of any issues that came up during the project (Figure 1).
After successful UAT execution and end-user training, the system was released to production and went live within the 38 day customer mandate.

**Enterprise IT Global Quality Management System (QMS)**

Sciformix’s overall framework for Information Security Management System (ISMS) and IT Quality Management System (QMS) is designed in accordance with ISO27001:2013, ISO9001:2008, ITIL V3, GAMP, ICH and other best practices. Being a state-of-the art IT QMS, it incorporates the latest regulatory guidance principles from around the world. The Sciformix IT QMS delivers quality excellence in 35+ IT process areas with specific work instructions for Argus project initiatives. This foundation facilitated the delivery of a fully regulatory compliant solution in record time.

**Virtualization Methodology and Standardized Validation**

In order to expedite delivery of a validated solution, our virtualization methodology was used in tandem with the IT-QMS to enable, implement, and validate the client-specific Argus instance in the Sciformix Safety Cloud. Sciformix maintains a controlled QA environment of Argus 8 single tenant base platform where all baseline qualifications and tests are performed. A “gold copy” of the QA environment is created using a pre-approved work instruction. This reduces the validation effort needed to commission the new customer-specific Argus environment on the Sciformix Safety Cloud to a few days (Figure 2).
Benefits to the Client

By implementing a flexible and integrated team structure, best-of-breed IT QMS and virtualization methodology, Sciformix was able to deliver a high quality validated solution in a record time of 38 days. The client:

- Achieved better consistency and control over drug safety continuum with a standardized safety technology environment
- Attained a cost-effective and unified system infrastructure by avoiding contracts with multiple legacy providers
- Realized a secure single tenant architecture with changes and planned system management downtime aligned with their business needs
- Experienced enhanced quality and compliance by being in a state of audit-readiness