



PV Operations & Argus Safety Database Merger

PROBLEM STATEMENT

A top 20 global pharmaceutical company needed to merge the PV operations and Oracle Argus Safety systems of two divisions into a single global operation running a single safety database.

- One of the two business units had previously committed to the health authorities that they would upgrade their pharmacovigilance system within a specified time frame
- Their goal was to partner with the pharmacovigilance department of another business unit within the same company to leverage that business unit's well-established technology, business processes, and global PV presence
- The project was behind schedule and commitments to the health authority were in jeopardy

SOLUTION

Foresight Group consultants were engaged to perform in four (4) months what had been originally planned to take a year by providing project management, PV business process and organization in addition to Oracle Argus Safety™ configuration, implementation and data migration skills to ensure timely completion of the integration.

Project Management

Foresight quickly reorganized the project structure and staffing and prioritized work streams. The project was broken into two phases with phase one being four (4) months to meet critical commitments made to health authorities by establishing the interim consolidated PV business operations and single safety database, and phase two completing over an additional six (6) months to perform the remainder of the business transition and legacy case data migration into the single safety database.

PV Business Transition

Foresight Group's PV business experts designed and implemented new end-to-end case processing workflows for case receipt through regulatory submission to support the business transition. Our team provided a detailed SOP analysis, and proposed revisions for all existing PV SOPs to expedite the client's document revision and approval cycles. Foresight defined the training curriculum for both drug safety application and processes, and managed all project communications to outside stakeholders.

CHALLENGES

- Time-sensitive commitment to health authorities and senior management for integration
- Limited ability of client to support needs of project due to increased workload associated with high-profile product
- Integration of business units necessary to improve efficiency, quality and compliance in case processing
- Two separate instances and versions of Oracle Argus Safety used across business units

SOLUTION

- Establish strict project management oversight and framework
- Implement targeted work streams with clearly defined objectives led by Foresight consultants who are experts in their respective areas
- Defined new PV process and executed business transition
- Merged safety systems into a single global instance



About Foresight

Foresight Group International AG is a global provider of drug safety and risk management professional services and solutions.

With over 200 employees in North America, Europe, Japan and India — we are the largest professional services firm in the world focused exclusively on drug safety and risk management.

Foresight provides all of our core services in both English and Japanese, including service desk for our managed services.

To learn more about Foresight, visit www.foresightgroup.com.

Core Services

- Hosting and Managed Services
- PV Process Design & Optimization
- Safety System Implementation
- Custom Reporting
- Signal Management
- Risk Management
- Inspection Readiness & Response
- Benchmarking and Analytics

Our People

- Experienced (average 8+ yrs.)
- PV process & systems experts
- Program managers
- Analysts and architects
- Developers and testers
- Many from industry
- Bi-lingual English & Japanese
- Local knowledge, globally

PV Business Operations & Safety Database Merger

SOLUTION (CONTINUED)

Using a global delivery model and support of a vendor, Foresight established an interim PV organization responsible to handle our client's global ICSR collection and regulatory reporting on a temporary basis, which allowed for an extremely rapid and fully compliant integration of central PV operations with minimal disruption to day-to-day activities.

After central operations reached "steady-state", Foresight engaged the client's network of affiliate safety representatives in 90 countries worldwide to implement legal agreements between entities, and allocate responsibilities from the interim PV organization to the global safety network. Foresight's business and technology experts worked together to re-configure the client's "reporting rules" to minimize over-reporting and correct under-reporting of ICSRs.

Foresight collaborated with the client's Quality Assurance, Clinical Development, and Regulatory Affairs departments, and their worldwide affiliates to ensure a seamless transition of responsibilities and robust links between all organizations.

Safety Database Consolidation and Data Migration

Foresight PV technology experts leveraged their safety system expertise to determine how to configure the client's Oracle Argus Safety system to run two business units within a single instance of the database and within a single unified workflow as defined by the business transition team.

Foresight's team conducted configuration workshops with participants from both divisions from both business and IT. The configuration was designed to support phase one and phase two use with no need to reconfigure the system as the business transition was completed and the interim CRO was replaced by the client's global country offices.

Foresight managed a team of client resources across four different countries and two business units along with an external vendor providing outsourced IT operations to complete the configuration work. Foresight then managed the validation effort and created many of the OQ scripts.

Finally, Foresight managed the completion of the data migration of legacy cases into the consolidated Oracle Argus Safety system and were instrumental in determining data mappings and transformations.

RESULTS ACHIEVED

- Streamlined project-related communications to stakeholders
- Negotiated multiple service-level agreements between organizations
- Implemented procedures to ensure case quality and timeliness of submissions
- Ensured a seamless continuity of business-critical and compliance-critical activities during the period of transition.
- Project management support by subject matter experts allowed client to work more efficiently on both the project and non-project responsibilities
- Robust project documentation to withstand scrutiny during inspection
- Improved efficiency, quality and compliance of case processing
- Met timeline promised to health authorities and senior management for business integration

www.foresightgroup.com

North America
119 Cherry Hill Road, Suite 230
Parsippany, New Jersey 07054
Telephone: +1.888.992.8880

Europe
Alpenstrasse 15
6300 Zug, Switzerland
Telephone: +41.44.586.27.36

India
904, 9th Floor, Tower-A,
Advant IT Park, Plot No. 7
Sector-142, Noida, U.P.
National Capital Region
Telephone: +91.120.451.5900

Japan
Kamiyacho MT Bldg 14F
4-3-20 Toranomon
Minato-ku, Tokyo-to 105-0001
Telephone: +81.3.6859.8461