

ORACLE Gold Partner
Specialized Oracle Argus Safety

CHALLENGES

- Merging the systems and PV operations of two companies
- Performing two data migrations within fifteen months
- Performing an Argus to ARISg data migration in parallel with an implementation of a new Argus system during the first half of the project
- Not all business users were supportive of performing the project — posing a change management challenge

SOLUTION

- Utilize Foresight's proven methodology for optimizing the implementation of Argus Safety™
- Retire the acquired company's safety system and organization during the first 18 weeks of the project
- Implement a new Argus Safety™ system
- Migrate from ARISg to Argus
- Author and deliver training on Argus to business and IT admin users

ARGUS IMPLEMENTATION, PV SYSTEM MERGER, AND MULTIPLE DATA MIGRATIONS

PROBLEM STATEMENT

A Top 30 pharmaceutical company purchased a smaller company. As part of the agreement, the regulatory obligations including pharmacovigilance were transferred to the new license owner. The acquired company had over 5,000 cases in an Argus safety database, and the buying company was operating an ARISg safety database with over 50,000 cases. The following issues needed to be resolved:

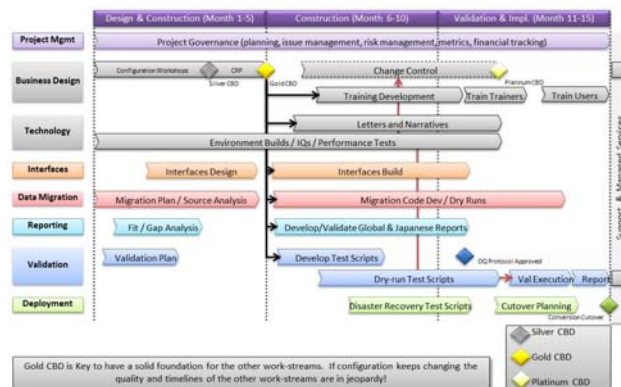
- In order to minimize the support required of two safety databases, the company did not want to wait for the new Argus implementation project before migrating the Argus data from the acquired company into their existing ARISg database
- The company needed to implement the new Argus system in parallel with retiring the acquired company's Argus system via a data migration into ARISg
- Expedited reports were being initiated via two separate processes and systems and the company wanted to move to one process and system as soon as possible
- The timelines were critical. The initial migration was targeted to be completed in 20 weeks to support a critical PSUR submission from acquired company's product via data migrated into ARISg

SOLUTION

Foresight was engaged to manage and perform both data migrations as well as the implementation of the new Argus system over approximately fifteen (15) months.

For the Argus to ARISg data migration, Foresight resources designed and implemented a solution using a direct data mapping approach between the two databases leveraging Foresight's Data Migration Engine. The project was completed within 18 weeks, 2 weeks less than the required timeline.

In parallel, Foresight performed a new implementation of Argus Safety™ along with a second data migration from ARISg to Argus following our proven Argus implementation methodology.



Foresight led the configuration, business design, installation, data migration, custom reporting, validation and deployment tracks of the project.



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

ARGUS IMPLEMENTATION, PV SYSTEM MERGER, AND MULTIPLE DATA MIGRATIONS

SOLUTION (CONTINUED)

- During the first third of the project Foresight designed the new configuration of the system through a series of workshops with client business users and then conducted multiple configuration pilots to confirm the new 'To Be' configuration
- For the data migration from ARISg to Argus, Foresight conducted an analysis of source data, then held data migration mapping workshops with business users to define a migration specification. Code was written, unit tested and then dry runs were conducted, a migration qualification was performed performing a series of automated and manual tests as per Foresight's migration methodology
- Foresight designed, coded and tested multiple custom reports
- Foresight created all IQ and OQ scripts and co-authored the validation master plan, and the trace matrices. We also assisted with PQ script creation and execution
- Foresight created business user and system administration training materials and conducted training on the new system
- Provided post go-live support for 2 weeks to business and IT users for addressing the learning curve on the new system features

RESULTS ACHIEVED

With the help of Foresight Group, the new Argus safety database and both data migrations were successfully completed and rolled into production in fifteen (15) months and the following benefits were realized:

- Two safety systems and PV operations were merged into a single system and single organization
- Argus to ARISg migration project completed ahead of schedule, enabling the acquired company's system to be retired early eliminating both system and business duplication
- Minimized impact to client resources
- Much of the work was able to be completed offsite, minimizing expenses to the client
- Enhanced features were implemented to replace manual steps leading to improved productivity by business users

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