



## SINGLE GLOBAL - JAPAN ARGUS / ARGUS J SYSTEM AND PV PROCESS

### PROBLEM STATEMENT

A Top 15 pharmaceutical company purchased two other midsized pharmaceutical companies and needed to consolidate safety database systems across all three entities. In addition, the company wanted to merge Global and Japan drug safety systems and processes into a single safety database and process.

The following issues needed to be resolved:

- The company had 7 different instances of Aris Global used in the United States and Europe with 100's of thousands of cases in a central database and some cases only existing locally within each regional instance
- The company was using ARISj™ in Japan with 10's of thousands of cases
- One subsidiary was using an older version of Argus with 10's of thousands of cases
- The other subsidiary was using a different version of ARISg™ also with 10's of thousands of cases
- Global and Japan business processes were not aligned within the parent company nor were system workflows or processes with the subsidiaries
- Existing reports for Global and Japan could not be reused for the new system and had to be reconciled and consolidated across all entities
- The company had failed multiple times on previous attempts to implement the new system, so a more reliable implementation partner and methodology was required to ensure success

### CHALLENGES

- Eight global data sources and a Japanese data source to migrate into a single safety database
- Gaining agreement on a harmonized process and workflow for Global and Japan within a single safety system
- Needed to provide local resources for both Global and Japan for both business and IT support
- Cultural and time zone differences between Global and Japan

### SOLUTION

- Utilize Foresight's proven methodology for optimizing the implementation of Argus and Argus J
- Implement a single safety database used by both Global and Japan
- Performed English and Japanese data migrations into a single system
- Created both English and Japanese custom reports
- Configured E2B for PMDA and global health authorities and license partners

### SOLUTION

Foresight was engaged to provide all Argus and Argus J implementation services which included program management for both Global and Japan, installation and configuration, custom reports for both Global and Japan and all data migrations for both Global and Japan.

The client wanted to execute the project in two phases:

1. Phase I was to consolidate all global systems and processing into a new implementation of Argus
2. Phase II was to combine Global and Japan into a single safety database and PV process by implementing Argus J and retiring ARISj™ in Japan.

Phase I  
Argus for  
Global



Phase II  
Add Argus J for  
single system for  
Global & Japan





### 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](http://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)

- Foresight's proven methodology for implementing Argus and Argus J was used. Phase I was completed in approximately 15 months and Phase II was completed about 9 months later
- Foresight staffed the project with both Global and Japan resources to ensure Japanese local language requirements were addressed
- Each phase followed the same full lifecycle methodology, except Japan was involved in both phases even though they were not going live on the new Argus / Argus J system until Phase II
- During the first third of the project Foresight designed the new configuration of the system through a series of workshops with both Global and Japan client business users present to ensure a harmonized configuration was created, and then conducted multiple configuration pilots to confirm the new 'To Be' configuration
- For the data migration from ARISg and ARISj 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 configured all E2B reports for health authorities and license partners, including reporting to the PMDA in Japan
- Foresight designed, coded and tested multiple custom reports in both English and Japanese
- 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 and Argus J safety database and both Global and Japan data migrations were successfully completed and rolled into production over two phases.

- Four safety systems and PV operations were merged into a single system and single organization
- Seven (7) ARISg regional instances, ARISg from a subsidiary, ARISj from Japan and the Argus from a subsidiary were all migrated into a single safety system successfully
- E2B reporting to the PMDA was successfully implemented
- The client is able to realize substantial savings on their IT and business operations spend by retiring duplicate systems and organizations

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