



ORACLE Gold Partner
Specialized Oracle Argus Safety

CHALLENGES

- 2.6 million global and Japanese cases to migrate and merging 300,000 duplicate global-Japanese cases into single cases
- Over 2000 active products, 16000 studies, 60000 licenses and 2000 reporting rules
- Gaining agreement on a harmonized process and workflow for Global and Japan within a single safety system
- Providing local resources for both Global and Japan for both business and IT support

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

SINGLE GLOBAL - JAPAN ARGUS / ARGUS J SYSTEM WITH PERCEIVE DATA MIGRATION

PROBLEM STATEMENT

A Top 10 pharmaceutical company needed to consolidate safety database systems across global and Japan, including operating pharma, generics, vaccines, consumer health and a joint venture into a single safety system. In addition, the company needed to integrate over 25 different systems with the new safety system and maintain a high degree of automation that existed within their global custom system.

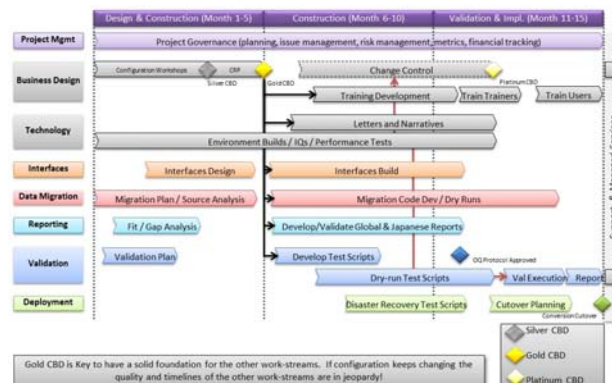
The following issues needed to be resolved:

- The company had over 2.6 million cases in their legacy global and Japanese safety systems that needed to be migrated into the new Argus / Argus J system, with duplicates between Global and Japan reconciled and merged into single cases
- The company was using Perceive in Japan with 100's of thousands of cases
- The system needed to be deployed to over 1000 users in over 80 countries simultaneously on day one
- 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 a high degree of automation within their existing custom global safety database that needed to be implemented within the new Argus / Argus J system — including implementing automation for Japanese cases

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, business process design and harmonization, SOP assessment, training creation and delivery (in both English and Japanese), custom reports for both Global and Japan, data migrations for both Global and Japan, creation of the Argus portion of all interfaces, and Japanese UAT.

The client wanted to execute the project in a single phase over approximately two and a half years using Foresight's proven methodology:





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

SINGLE GLOBAL - JAPAN ARGUS / ARGUS J SYSTEM AND PV PROCESS WITH PERCEIVE DATA MIGRATION

SOLUTION (CONTINUED)

- Foresight's proven methodology for implementing a single instance of Argus / Argus J for use by both Global and Japan was used. The project was successfully completed in about thirty months with rollout to over 80 countries and 1200 users simultaneously day one.
- Foresight staffed the project with both Global and Japan resources to ensure Japanese local language requirements were addressed — with Japanese resources being dedicated on-site at the client office in Tokyo.
- 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 their global custom system and Perceive in Japan to Argus/Argus J, 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. Over 2.5 million cases were migrated.
- Foresight configured all E2B reports for health authorities and license partners, including reporting to the PMDA in Japan. In addition many custom E2B profiles were created for importing and sending cases to/from license partners. There are over 120 partners configured within the system.
- Argus Affiliate was implemented for over 60 country offices.
- Configured over 2000 active products and over 16000 studies with over 60000 licenses with over 2000 reporting rules and over 500 destinations
- Foresight designed, coded and tested multiple custom reports in both English and Japanese
- Provided post go-live support for 4 weeks to business and IT users for addressing the learning curve on the new system features
- Foresight is contracted to provide Argus related managed services post go-live for the new system.

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.

The client performs over 2000 submissions per **day** using the new system.

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 Toranomom
Minato-ku, Tokyo-to 105-0001
Telephone: +81.3.6859.8461