ORACLE’S ARGUS SAFETY JAPAN: A SINGLE GLOBAL DATABASE FOR WORLD-WIDE PHARMACOVIGILANCE

Language barriers and a complex regulatory environment make Japan one of the most challenging markets for health sciences companies to ensure regulatory compliance. Oracle Argus Safety Japan, Oracle’s solution for submission of expedited and periodic reports to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), enables pharmaceutical companies to fully integrate Japan into the global business process while addressing Japan-specific pharmacovigilance challenges.

Supporting Global Regulatory Compliance
Argus Safety Japan supports the life sciences industry’s global reporting requirements. It delivers comprehensive coverage of Japanese regulatory reports to PMDA, including Expedited and Periodic Safety Reports (PSR). It also supports global compliance for all expedited and periodic safety update reports (PSUR) for the International Conference on Harmonization (ICH).

Argus Safety Japan leverages Argus’ single global database for superior compliance capabilities. Pharmacovigilance staff can focus on effective safety information management, regardless of where in the world the case originated. In addition, Oracle offers extensive expertise in Japanese regulations, as well as a large ecosystem of Japanese partnerships, ensuring that Argus Safety Japan will remain in compliance to support Japanese clients’ evolving regulatory requirements.

Enabling The Global Pharmacovigilance Business Process
For health science companies with global operations, Argus Safety Japan integrates seamlessly with Oracle Argus Safety, providing a single global database with unified workflow for management of worldwide drug safety information. With a single global database for safety, reporting and analytics, and an integrated global workflow that facilitates compliance and safety, it delivers major process efficiencies to significantly lower the cost of global pharmacovigilance.

Companies realize productivity gains from Argus Safety Japan as it completely eliminates double data processing efforts, reduces translation efforts and vastly speeds up the time to manage and report a safety case with capabilities such as:

• global case monitoring
• advanced translation features, including a split-screen view
• auto-narratives
• auto-coding
• auto-scheduling

Argus Safety Japan’s single global database reduces IT overhead while its truly global configuration also improves manageability and simplifies system maintenance for administrators.
CONSULTING SERVICES
Oracle offers a complete suite of consulting and training services that help customers implement and become productive with Oracle Argus Safety Japan as quickly as possible.

ORACLE’S ARGUS SAFETY JAPAN TECHNICAL SPECIFICATIONS
- Client:
  - Windows XP Pro SP3 (English and Japanese) (IE7 or 8), and Vista SP1 (English and Japanese) (IE7 or 8).
- Middle Tier:
  - Windows 2003 R2 (English), Windows 2008 SP2 (English)
- Database:
  - Oracle 11g

Argus Safety Japan’s single, global database and integrated global workflow delivers major process efficiencies to significantly drive down pharmacovigilance costs for companies doing business in Japan.

Addressing Japan-specific Pharmacovigilance Challenges
As life sciences companies develop and commercialize their products, they face a myriad of challenges in meeting requirements unique to Japan. Argus Safety Japan addresses these Japan-specific business processes and provides comprehensive translation support and a localized interface to improve pharmacovigilance efficiency. These include:

- **Single Global Database** – Japanese user can have single case data including the English information. Data entry is optimized to reduce translation work while case processing is fully integrated in the global workflow
- **Fully compliant with PMDA** – All Japan-specific reports mandated by PMDA are supported, in addition to the global reports
- **Localization** – In addition to the full Localization on Case Form UIs, E2B Check-error messages, Worklists, regulatory reporting tools and Personal Argus Status have all been localized
- **Enhanced Case Form** – Case Form has many Japan-specific additional features to support Japanese user’s business needs:
  - Split screen allows the user to conveniently view English and Japanese Case Forms in a single screen
  - PMDA tab for recording all E2B J items information, and generating multiple PMDA reports from a single case
  - Auto translation for all selectable fields
  - Auto MedDRA and MedDRA J encoding
  - Lab data Import/Export
  - Reporter Information Search based on the institutions
  - Master table loading and its dictionary searching capability
- **PMDA specific E2B mapping and E2B check rule. Japan specific ICSR Validation** – provides system check for Japanese regulatory reporting, and user configurable Japanese E2B attributes
- **Expanded reporting** – Due-soon calculations considering Japan information receipt date, as well as a Holiday Calendar to adjust report date schedule
The Oracle Difference

Argus Safety Japan is designed specifically with Japan’s requirements in mind and is completely integrated with Oracle Argus Safety for streamlined case management and worldwide electronic submissions. It is continuously enhanced through a defined and planned product roadmap.

Oracle’s expertise in Japan, speed of release and dedicated Japanese staff, ensure that Argus Safety Japan continues to meet regulatory compliance, supports operational excellence and helps lower the cost of pharmacovigilance.

Contact Us

For more information about Oracle’s Argus Safety Japan, please visit oracle.com/healthsciences or call +1.800.ORACLE1.