Register

COMPREHENSIVE REGULATORY INFORMATION TRACKING AND SUBMISSIONS MANAGEMENT

The global regulatory environment is converging and getting more complex. The rate of this change is increasing. The role of Regulatory Affairs has evolved as the custodian of central product data repository and compliance related information. It is now critical in ensuring successful product registration in each market for pharmaceutical, biotechnology and medical device companies. Often, Regulatory Affairs teams have to rely on manual, disconnected or semi-automated IT systems to support their daily activities. This inefficient process relies heavily on individuals to manually maintain a product portfolio while ensuring compliance, and has the potential for serious unwanted consequences. The number of products, updates, variations and potential markets is always increasing. This makes control of registration activities increasingly complex. Register™ helps simplify and enhance the efficiency of these workflows. Organizations also have the convenient and cost effective option of using Register in ArisGlobal's proven Cloud environment – agCloud™.

Key benefits

- Manages the registration, renewal and re-registration process
- Provides immediate access to submission status and history
- Facilitates centralized management of dossiers for all types of regulatory submissions
- Supports end-to-end Medical Device registration process
- Integrates easily with SAP®, Documentum®, SharePoint®, eCTD publishing and labeling systems
- Supports central and affiliate access for effective collaboration and communication
- Monitors regulatory commitments and correspondence with the agencies
- Enables collection, compilation and management of regulatory intelligence

Comprehensive Solution for Regulatory Affairs

Register is the market-leading solution for planning and managing global product portfolios with end-to-end regulatory tracking. It is a commercial software application that effectively tracks registration statuses worldwide including in the USA, EU and Japan. It stores and manages information collected from multiple sources. Register allows authorized users to track and monitor a drug product, country-wise information and company-specific registration data globally or locally. Register gives all regulatory affairs stakeholders a holistic view of the entire business. It provides specific and personalized management reports for planning, tracking, analyzing, studying trends, decision-making and monitoring the registration statuses of products. It is a J2EE-compliant application that requires only an Internet browser and includes multi-lingual and localization support.

Facilitates Global Compliance for Medical Devices

For Medical Device manufacturers, meeting all national and international regulatory requirements is a significant challenge. With evolving requirements and standards, manufacturers can utilize a Regulatory tracking and submissions management software application to quickly comply with regulatory requirements. Register enables real-time tracking throughout every step of the device registration process.

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It helps automate the process of medical device registration using criteria that the device manufacturer has established. It can help automate many repetitive and time consuming tasks leading to a more effective business model. The many additional benefits of using this software application will lead to an excellent return on investment, which directly leads to a more profitable company.

Full Regulatory Control

Register's intuitive, user-friendly design allows for easy configuration and deployment throughout an organization, providing regulatory departments with the ability to meet internal and external requests, while simultaneously managing all global registration activities. Compliant with the latest regulatory guidelines, Register tracks all regulatory activities (including CP, DCP, MRP, etc.) and helps organize submission project planning and tracking. It also facilitates management of questions and correspondence, tracking of variations, amendments, re-registrations, and renewals.

Register supports the xEVMPD initiative and, when combined with ArisGlobal's agXchange RSM™ system, offers a unique solution for the exchange of product data with regulators. Data can be seamlessly shared with safety systems so that coding of ICSRs and SUSARs (E2B) is compliant with the approved regulatory data (DMPs/AMPs).

Centralized Dossier Management

Register helps users in centrally-defining and managing dossiers for initial and variation submissions. This allows for dossiers to be re-used for different product strengths, dosage forms, etc. as, in these cases, most of the documents are exactly the same. It also enables re-use of dossiers across different registrations in a group procedure, or when distributing multiple waves of submissions.

Open Integration with SAP

Register's open design allows easy integration with key systems such as document management systems, labeling, manufacturing and pharmacovigilance to reduce the complexity of maintaining separate data pools and of sharing information. SAP composites can be provided that support full-integration with the SAP manufacturing system as well as facilitate quality control and manufacturing compliance. For further efficiency gains, Register can be deployed on the SAP Netweaver® platform and is delivered with iViews that can be displayed on the SAP NetWeaver® portal.

A Proven Solution from the Market Leader

Register is the market-leading solution that is helping the largest life science organizations to establish full control of all regulatory affairs activity on a global basis. With Register, users and senior management have all the necessary information in a single, integrated solution to make intelligent product decisions across the organization.

About ArisGlobal®

ArisGlobal is a leading provider of integrated software solutions for pharmacovigilance and safety, regulatory affairs, clinical research and quality and compliance. Hundreds of life science companies rely on ArisGlobal's advanced solutions for maintaining regulatory compliance, workflow automation, improving operational efficiency and easily sharing information around the globe.

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Software solutions for life sciences