

Used by 20% of the top 50 pharmaceutical companies, including four of the top ten, Register™ is the market-leading solution for centrally managing products and tracking global registrations. Organizations have a single, integrated regulatory submission software solution for establishing full control of all regulatory affairs activity on a global basis.

The following are real-world success stories from some of the companies that use Register to effectively manage product portfolios and track regulatory submissions.

## Ensuring global compliance with a single source of authoritative data

One of the world's largest pharmaceutical and health product companies struggled with global compliance due to manufacturing facilities and export operations in numerous countries. Various divisions and affiliates used a number of different systems in an attempt to manage regulatory affairs. But the lack of comprehensive functionality and minimal integration with established business processes impacted its ability to fully understand global regulatory implications and the potential cost of a proposed manufacturing change prior to execution.

The company recognized it needed a solution that would

enable efficient sharing and access to product information across the various business functions to help maintain worldwide compliance between the manufacturing processes and the corresponding Marketing Authorizations. After an extensive vendor and product selection, the pharmaceutical giant selected Register to be the single, global authoritative source for regulatory information.

Since Register was implemented, the company has replaced manual and redundant regulatory tracking systems with a unified user interface. Register is now the central repository of all registered information and established robust change control across affiliates, regions and manufacturing plants in more than 100 countries. The regulatory product information stored in Register is used to support many key global business processes and is critical to ensuring compliance with registration maintenance, change control and safety reporting.

“Register is now the central repository of all registered information...”

### Benefits

- Provides single, global authoritative source for regulatory information
- Enables smarter, better, and faster business decisions
- Eliminates manual and redundant regulatory tracking systems
- Provides enterprise-level, authorized access for all business processes
- Exposes and aligns regulatory information

## Monitoring post-marketing commitments and obligations across markets and product lines

Multiple, localized systems for regulatory event information presented a global research-driven pharmaceutical company with the challenge of distributing critical product details throughout their organization. Its regulatory community with multiple locations and jurisdictions made tracking product registrations and renewals in each market a significant challenge.

The organization selected SAP<sup>®</sup> to manage the product portfolio and manufacturing operations and realized that continuous, collaborative compliance is needed in every aspect of the drug development and product lifecycle. The company deployed Register for all regulatory events tracking information for all submissions. Standards were developed to represent all products and submissions.

“Continuous, collaborative compliance is needed in every aspect of the drug development and product lifecycle.”

### Benefits

- Reduces costs by consolidating systems
- Enforces standards across geographic borders
- Ensures compliance with regulatory requirements
- Bridges compliance gap between regulatory and manufacturing

Today the company leverages Register for keeping track of the approval details (such as shelf life, packaging code, etc.) in each market before manufacturing releases the batch for shipment. Register is also being implemented to track and manage all post-marketing commitments and interactions with the regulatory authorities. From a single dashboard, management can monitor the company's commitments and obligations across markets and product lines.



## Streamlining and supporting simultaneous submissions

In order to support global expansion, this major pharmaceutical company was challenged with ensuring that regulatory and product data across multiple systems were in agreement. The organization was looking at different ways of harmonizing the regulatory process and addressing unique requirements across a global environment while keeping an eye on simultaneous submissions. Management required the need to have real-time metrics, which was customized to the region and product line with the ability to drill down into the details.

At headquarters, Regulatory Affairs were also looking to automate the monitoring of the local affiliates and streamline the submission process in support of simultaneous submissions, dossier component reuse and post-approval lifecycle management.

The company implemented

Register as the central location for managing and validating detailed product details and distributes the regulatory data to global affiliates. Register enables headquarters to monitor the registration status and history across geographic locations and automatically alerts management regarding new milestones, major product variations, and post-marketing commitments. Register is also being used with agXchange RSM™ (Regulatory Submissions Module) for the submission of the EudraVigilance Medicinal Product Dictionary (EVMPD) product data as requested by the EMEA.

“Register automatically alerts management regarding new milestones, major product variations, and post-marketing commitments.”

### Benefits

- Stores, maintains and validates product information worldwide
- Maximizes revenue opportunity by effectively managing and controlling authority requests and regulatory commitments
- Distributes real-time regulatory data

## Managing end-to-end regulatory tracking for a diverse product portfolio

One of the top ten global generic pharmaceutical companies had been dealing with multiple information silos for managing its products, registrations, and variations. Faced with a very manually intensive process for maintaining variations across all the countries they serve, the company was looking to gain central control over its products and numerous manufacturing sites.

With a growing global footprint, it became essential to have a regulatory information management solution that would support its market penetration into various regulated

markets. Register has been implemented at its corporate headquarters and is helping the company manage the end-to-end regulatory tracking of its diverse product portfolio across 49 countries and manufacturing operations in 11 countries. Register acts as the central repository, storing and managing information collected from multiple

sources. Authorized users can track, monitor and view the drug product, country and company-specific registration data at the global and/or at the local level.

The company maintains detailed information, including product type, product line, product name, formulation, composition, packaging (primary and secondary), as well as detailed manufacturing information such as sites, tests, and steps. Register facilitates filing and tracking variations and renewals while establishing change control across products, plants, affiliates and regions.

“...the company was looking to gain central control over its products and numerous manufacturing sites.”

### Benefits

- Enables real-time monitoring of the global business
- Provides easy access to regulatory information
- Reduces internal development costs

### About Aris Global<sup>®</sup>

For more than 20 years, Aris Global has been a trusted and reliable partner of many of the world's leading pharmaceutical, device, biotechnology and clinical research organizations. More than 300 life sciences companies rely on our innovation and advanced technology solutions in pharmacovigilance & safety, regulatory affairs, clinical research and medical information.

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