Case Study

PMS-Integrated Product Registration Tracking

ABOUT MEDICAL DEVICE CUSTOMER

As one of the world's largest biotech firms and the fifth largest pharmaceutical company, our customer needed an integrated digital solution to efficiently plan, track, and report on worldwide product registrations. Managing vast product and registration data in a single system posed significant challenges, including cost and time constraints.

OPPORTUNITY

Managing a large product catalog through ERP alongside a spreadsheet tracker was challenging, and direct submissions to health authorities weren't feasible:

- With a large product range, our customer dealt with data management challenges, including manual documentation and high transaction volumes. Additionally, navigating registrations with 80+ country regulators was both expensive and time-intensive, leading to delays and compliance setbacks.
- With product registrations stored in siloed spreadsheets and paper files (unconnected to manufacturing changes), RA teams had to manually track updates - leading to delayed approvals and higher compliance risks.

- The company struggled with uncontrolled document access, as paper-based records were stored in a shared drive by multiple employees, raising compliance risks.
- Monitoring registered product statuses manually, without automated standardization or self-generating country templates, created complexity and hindered overall process efficiency.

SOLUTION

Smarteeva deployed a Product Registration package that integrates content management, intelligent data automation, and sophisticated reporting logic into a single unified system:

- To ensure the system is updated with accurate data daily, a continuous integration pipeline connects ERP and Smarteeva.
- Smarteeva developed a centralized solution for managing regulatory reporting workflows, which features end-to-end project tracking and integrated collaboration capabilities.
- Smarteeva enabled users to preview reports in real-time and generate regulator-ready outputs with a single click in multiple formats, including PDF, Word, and XML.
- Users get pre-built, smart report templates that ensure consistent formatting and automatically apply the correct regulatory rules for any market or report type.
- To automate data retrieval and reporting, Smarteeva's intelligent connectors seamlessly link Material Groups with their related product and registration data.
- To ensure quality, Smarteeva uses an embedded multi-stage workflow that guides document sections through a defined path of reviewers and approvers before the report is finalized.
- By logically organizing similar devices, Smarteeva optimizes reporting, streamlines data management, and eliminates duplicate submissions.
- Using Smarteeva's "Template Configuration" interface, organizations can configure templates to define reusable structures for generating a wide range of compliant regulatory reports.

- Smarteeva seamlessly integrates with the company's data sources, such as registrations, sales, and incident databases, to automatically populate tabular data.
- Our platform provides intelligent report sections that dynamically generate and customize content based on predefined project and compliance requirements.

RESULT

Global product registration, automated and unified

- Smarteeva's automated Product Registration system revolutionized our client's approach to their product portfolio and global visibility. Our integration with their RIMS simplified the entire registration workflow, eliminating the time, resource, and expense burdens of manual categorization and process management.
- Our primary focus remains on delivering ultimate value to customers by expanding our AI-enabled products to reform Post Market Surveillance and medical device reporting.