

GLOBAL REGULATORY INFORMATION MANAGEMENT – A CASE STUDY



CHALLENGE: SOLVING THE INFORMATION MANAGEMENT PROBLEM WITHIN A GLOBALLY-DISTRIBUTED REGULATORY OPERATIONS GROUP AT A LARGE, PRODUCT DEVELOPMENT AND MARKETING COMPANY.

Solution: A web-based product management solution to manage all regulatory operations activities globally, including products, submissions, contacts, agency commitments, CMC information, State Licenses, Central Files etc.

The Client:

The client is one of the world's foremost public, product development companies with multiple drugs and devices developed and marketed internationally.

Business Need:

The company currently markets dozens of active products in multiple countries, with many more drug and device candidates in the pipeline. Given the multiple regulations, agencies and countries involved, the company faced a number of challenges in managing and tracking global product submissions, registrations and on-going maintenance submissions. The company also needed to standardize regulatory processes, consolidate information and provide timely reporting of regulatory information, including interactions with global regulatory agencies, across all its locations worldwide.

Solution:

Virtify developed and implemented a web-based enterprise, 21 CFR Part 11 compliant, electronic-records management system that allows authorized users to track and manage key regulatory information and milestones. The system allows for enhanced collaboration and access to key information and enables effective knowledge management. The system supports regulatory decision making by providing current, accurate regulatory information in a centralized database, with integration to other key data sources such as the company's enterprise safety/ Adverse Event Management system, global portfolio and project planning system and other clinical systems. Key features of the system also include high usability, performance, scalability, robustness and enhanceability of the application.

Virtify used its proven requirements definition and analysis methodology to enable the client to develop the requirements for the system that optimally addresses its needs. During the engagement, a phased approach consisting of the Requirements Gathering, Current State Assessment, Requirements Finalization, Roadmap Generation and Implementation/Rollout phases were used within a structured project management framework to develop the required project deliverables. Specifically, a Virtify team consisting of relevant domain experts, along with key client stakeholders worked in a tightly integrated project team to develop the deliverables of this project, including a complete system requirements document and a roadmap for the implementation of the system. Specific activities include:

- Generating business and end-user requirements using facilitated workshop, interview sessions, checklists and related requirements gathering tools.
- Performing a current state technology and process assessment, and identify gaps based on the business and end-user requirements.
- Developing a plan to address the identified gaps for the optimal solution.
- Finalizing a roadmap for the solution implementation.
- Designing the solution on an open, multi-tiered, standards-based architecture.
- Developing the entire system.
- Complete implementation, including computer system validation and rolling out of the system globally.

The system is currently in use in over 80+ countries with hundreds of regulatory operations and management users.



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Benefits:

The system facilitates global regulatory compliance by providing immediate access to product characteristics, worldwide submission and registration data, key milestones, filing plans and internal regulatory activities. Key benefits include:

- Enhanced planning and tracking of global regulatory information.
- Comprehensive management of regulatory contacts and related commitments to regulatory agencies worldwide.
- Linked contacts, commitments to regulatory agencies and associated documentation.
- Improved collaboration and productivity within the regulatory affairs group.
- Centralized access to information on global product submissions and approvals.
- Seamless integration of document management functionality.
- Integration of submission information to safety and adverse event information.
- Integration with portfolio planning tools for milestones tracking, planned vs. actual milestones etc.
- Centralized compliance management for state licenses and facilities filings.
- Centralized event and calendar management.
- Powerful keyword and advanced search capabilities.
- On-demand structured and dynamic reporting of key metrics, milestones and performance measurements.
- Proactive alerts for upcoming deadlines, filing and compliance milestones.
- 21 CFR Part 11 Compliance.
- Roles-based access control and security for both data and system functionality.
- Quick access to and management of QA and manufacturing information.
- Web-based, 24/7 access to global regulatory information.
- Standardized regulatory processes and consolidated product information across all its locations worldwide.

About Virtify

Virtify is a global company, with headquarters in Cambridge, MA and other international locations in India, Philippines and Bulgaria. We use cutting edge web-based technologies and global delivery capabilities to develop and implement innovative software products and solutions for the Life Sciences industry.

One of our strengths is our deep domain knowledge and demonstrated leadership in emerging global standards. Virtify is one of the first companies to introduce a pure web-based Structured Product Labeling (SPL) solution for managing the entire life cycle of labels. Virtify was the first to submit a SPL demo to the Food and Drug Administration (FDA) and the first company to submit a Regulated Product Submission (RPS) drug device and combination drug submission to the FDA. The first RPS Viewer was also introduced by Virtify we were the first to submit an Electronic Common Technical Documents (eCTD) drug and device submission to the FDA. In addition, we have recently been the first to submit messages in emerging standards such as eStability and ICSR. Such leadership on standards has enabled us to work closely with clients in effectively planning for emerging standards while addressing current mandates and standards for clinical and regulatory submissions.

Virtify's clients include several pharmaceutical, biotechnology, medical device and animal health companies, and its projects have spanned the R&D lifecycle, from discovery through commercialization. For information about our offerings, please contact us at:

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