

# DOCUMENT LIFE CYCLE MANAGEMENT

## A CASE STUDY



**CHALLENGE:** AUTOMATING THE DOCUMENT LIFE CYCLE PROCESS ACROSS MULTIPLE, GLOBALLY-DISTRIBUTED FUNCTIONAL GROUPS INVOLVED IN CREATING CLINICAL AND REGULATORY SUBMISSIONS.

**Solution:** A comprehensive web-based solution to manage all document creation, review, approval and related lifecycle management activities, including metrics reporting.

### **The Client:**

The client is one of the world's foremost biotechnology companies with annual revenues exceeding \$3 billion and 10,000 employees in locations spanning the globe. With many established drug products and services helping patients in nearly 90 countries, it is a leader in the effort to develop and apply the most advanced technologies in the life sciences.

### **Business Need:**

As the size of the company grew from a start up to a diversified global enterprise with multiple product lines they faced frustration with a lack of document management solutions that could adequately manage fast business growth and focus on streamlining the document life cycle management processes within the context of regulatory mandates issued by Government and regulatory agencies worldwide. The company wanted to build a solution that would help manage the document life cycle processes across multiple, distributed functional groups involved in creating clinical and regulatory submissions.

The company established a Document Life Cycle Process Improvement initiative internally to identify the internal processes and a suitable solution. The initiative determined that challenges were within the authoring, reviewing and approval processes. The lack of standardization, movement of documents between the document management system and file systems introduced redundancy and inconsistency with a high degree of error. Further, the processes were manually intensive with limited technology automation. The situation also was compounded by the mandates to standardize regulatory documents and elimination of paper.

The lack of the functionality available within conventional document management systems with regard to standardization and compliance to standards such as ICH, HL7, CDISC and others prompted the customer to identify a solution. Specifically, the customer was looking for a solution that will offer a richer Web 2.0 User Interface experience, personalized views, enforce standardization and compliance both internal and external standards, adaptable to the changing regulatory standards, integrate with the existing document management system and to be able to generate metrics and statistics on the document life cycle processes.

### **Solution:**

The customer chose Virtify's Virtx DLM as the solution to meet their business needs after evaluating 15+ solutions in the market including conventional document management systems. They used the software to create a compliant standards based environment that can be used by employees globally to find accurate and consistent information that they need immediately and connect with the right people when they need fast answers. Everyone is more productive, less frustrated, and able to make faster, better-informed decisions. The web based solution ensures that there is a single access point to manage the document life cycle processes and a single repository to store documents thereby supporting improved regulatory compliance.

Virtx DLM helps standardize document life cycle processes within an organization namely the authoring, reviewing, publishing, approval and archival processes. This standardization eliminates inconsistencies and improves efficiencies by efficient usage of the resources, infrastructure and time. Virtx DLM provides businesses with the simplest way to get the power of Virtx Platform, Virtify's standards based platform built on ISO, W3C, ICH, HL7, CDISC and other standards. The product features modules for collaborative authoring, reviewing, support for simple and compound documents, versioning, workflow, automated publishing, process metrics and statistics plus security, search, reporting and integration modules.

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**Benefits:** (continued from previous page...)

Adopting Virtx DLM with Software + Services model and partnering with Virtify have helped the client reach achieve its near terms goals with regard to improvement of existing document life cycle processes by introducing technology automation and standardization. The solution is also designed to address long term strategic goals as the company's business continues to grow and as the business is subject to changed introduced by external regulatory mandates. The following are some of the key benefits that the customer has realized based on the implementation of the solution:

- Reduction in the risk of inadvertent use of inconsistent or outdated document content – The centralized access control mechanism and versioning system ensures that the system makes available the right version of the document content to pertinent groups. This eliminates the risk of using duplicate copies on multiple systems including document management systems, network drives or user desktop that may be inconsistent or outdated.
- Increase in the efficiency of resources, e.g., reduce document cycle time – The utilization of technology to automate process milestones ensures that the efficiency of resources is greatly increased. Resources can focus more on the content generation as the system automates the process milestones, standardization and compliance to regulatory standards.
- Automate process milestones and enable metrics and reporting – The underlying platform within the system offers capabilities to enable metrics and reporting on process milestones. The process milestones and metrics such as # of review/approval cycles by type of document, # of comments per document per user and others can be used to continually improve and re-engineer processes where deemed necessary.
- Ensure regulatory compliance in a robust and explicit manner - With all the documents managed within a single repository and a single web based secure access for all of its employees, the company now has a better audit trail of its document life cycle processes, both for regulatory compliance and continuous process improvement.

## 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:

Virtify, Inc. 55 Cambridge Parkway Suite 410 Cambridge, MA 02142 United States of America

Tel: +1 617.252.0770 Fax: +1 617.812.0378 Web: <http://www.virtify.com> E Mail: [info@virtify.com](mailto:info@virtify.com)

