

STRUCTURED CONTENT AUTHORING

A CASE STUDY



CHALLENGE: ESTABLISHING A STRUCTURED CONTENT AUTHORING ENVIRONMENT ACROSS THE ENTERPRISE.

Solution: A template-driven solution that allows for multiple authors to collaborate and create standards-based XML documents (without the need to have knowledge of XML).

The Client:

The client is a leading manufacturer of injectable pharmaceutical products covering a wide range of therapeutic areas. With global operations and over 1400+ employees, the company's products aim to provide affordable health-care to millions of people worldwide.

Business Need:

The emergence of standards based on XML by worldwide regulatory agencies such as FDA, EMEA, MHLW and others required life sciences companies identify a solution that would comply with the new requirements. The existing systems, infrastructure, resources and processes were designed to handle traditional paper based output and/or MS-Word, Excel, PDF, etc. type of outputs. The company needs to submit submissions to regulatory agencies worldwide to meet its internal business goals and comply with regulatory commitments. A submission consists of various documents that are organized in a prescribed structure. These submissions are an indicator of the company's development and progress, so processing them on a timely basis is critical to its business goals.

Typically, the company processes and submits approximately 100 submissions on a monthly basis. Most submissions are between 50 and 5000 pages—the average is 100 to 250 pages—which add up to a stack of multiple volumes of paper. The documents within these submissions contain paragraphs, tables, lists, images and may include pagination, formulae along with detailed formatting, presentation rules.

The company had been using a solution comprised of desktop authoring tools such as MS-Office, Adobe PDF, publishing tools such as PDF toolkits/add-ons, Office to PDF converters with document management systems, network drives and local desktop to access and store documents. The authoring tools were used to author and review content and the publishing tools were used to generate the PDF version of the document. In addition, the PDF toolkits/add-ons were used to manually generate and QC TOC, TOT, TOF, bookmarks, hyperlinks, etc. In most cases, the publishing group had to re-format the approved source documents from the authors in order for them to be ready for processing using the publishing tools.

With the new regulatory requirement to generate the document in XML, the company utilized an out-sourcing approach where the source document was sent to a vendor and the vendor would send them the XML output. While the process worked it was highly inefficient and prone to errors. The manual publishing process was labor intensive and would typically require 4-8 hours of a skilled resource to publish and QC an average size document. The vendor cycle time for the XML version would typically be in the order of 2-3 days depending on the size of the document. Additionally, these documents are subject to last minute changes as the company negotiates the language within the document both internally as well as externally with the agency. Each change requires re-publishing the document and conversion to XML. The nature of this process slows down the processing time of submissions with risk of errors and not being able to meet regulatory commitments on time.

The manually intensive and in some cases redundant process caused by the lack of authoring standards, constant updates, formatting, manual publishing and XML conversion slowed down the submission process and compromised the overall benefits of automating a critical business process. When a document takes ~ 4-8hrs to publish and QC depending on the size of the document with the possibility of changes it adds uncertainty and randomness to what should be a completely predictable operation. This manual process wasted hours every month and relied on accuracy and efficiency of the submission staff.

To management at the company, this translated into very long project timelines for submissions to process and be delivered to the agency. Overall, this lack of standard processes and automation capabilities disrupted the organi-



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organization's workflow on an issue as important as processing submission documents.

The company started researching solutions that would help address the issues and decided to implement a Web based collaborative authoring solution that would help standardize the authoring processes (templates, formatting, styles, etc.) and automate publishing activities. In addition, the solution would enable generation of different formats including MS-Word, PDF, XML, HTML, etc. from a single source document. This would eliminate the manual publishing process as well as the dependency on the XML vendor to generate the XML output. Furthermore, the authors can continue to make changes and dynamically generate various outputs on demand at any time.

Solution:

The customer selected Virtify's Virtx Web Authoring solution to meet their authoring and publishing requirements in order to meet their overall submission timelines efficiently. The Virtx Web authoring solution combines the richness of a word processor interface with server based publishing. The authoring interface is similar to a conventional word processor delivered via the browser to enable multi-user authoring experience. The template driven nature of the interface allows users to easily customize document structures and formatting rules including font styles, font type, heading levels, header/footer, etc.

The automated publishing interface offers the capability to generate different output formats including XML, HTML, Word, PDF and others. The solution also offers both document and section level version control/roles based access within a secure integrated compliant environment.

Benefits:

The company is benefiting from robust, dynamic document authoring and automated publishing process. The new solution requires no learning curve as the interface is similar to conventional word processor including shortcuts, icons with the option to copy and paste from Word. The new solution delivers impressive performance improvements.

A document that took 4- 8 hrs to process now takes less than 10 min to publish to multiple formats including generation of TOC, TOT, TOF, Bookmarks and hyperlinks. Formatting issues which required re-formatting documents were no longer necessary as the system enforced the formatting styles automatically. The convergence of technology and process eliminated the company submission process related bottlenecks.

The company has gone from a manual desktop based publishing system to unpredictable timelines to an automated system with a predictable timeline. The company is enjoying the benefits of a completely automated billing process. The Web 2.0 interface and architecture has increased organizational productivity and reducing overall deployment and maintenance/support costs.

Although this solution addresses only the submissions business process it is a critical function that affects the entire company's goals. Efficient submission processing and delivery not only ensures that regulatory commitments to agencies and company goals are met on time or quickly but also provides competitive advantage and improves the company's image.

With the elimination of manual processing the company is saving hours every month on manual publishing, re-formatting, out-sourcing, troubleshooting problems and submission processing times have dramatically improved. The table below summarizes at a high level the productivity improvements after implementing the Virtx Web Authoring solution.

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Submission Activity	Before Virtx WA	After Virtx WA	% Improvement
Average processing time for submissions	2-4 weeks	1 week	Up to 66%
Average time spent of re-formatting a source document prior to publishing*	2-4 hours	0 hours	100%
Average Publish and QC time for a source document*	4-8 hours	1 hr	Up to 85%
Average time spent of re-processing due to changes in source content*	4-8 hours	30 min	Up to 95%

* - Time indicated in table is for a average single document between 100-250 pages and does not include time to convert document to XML

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

