Streamlining Regulatory Publishing with Submission-ready PDFs

By Scott Mackey

Introduction

As the business world turns its attention from back office automation to front office efficiency, the need to streamline document and information management is starting to play an increasingly important role. Nowhere are stakes higher than in the pharmaceutical industry where a day's delay can mean millions against the bottom line – and when the product might mean the difference between life and death for millions of people worldwide.

Although Enterprise Content Management applications, eCTD (electronic Common Technical Documents) software and other information management tools all provide benefits designed to better manage information and streamline document workflows, government and regulatory mandates leave a lot of room for increased efficiency.

The Regulatory Minefield

Time to market is often held hostage by the global regulatory landscape, but few industries face regulation on the same scale and level of complexity as life sciences companies. It is surprising, then, how often the key results of research are compiled and maintained on nothing more sophisticated than a series of unmanaged Microsoft Word documents and even hand-written forms.

Submission documentation often consists of hundreds of thousands of pages. Extend this over multiple jurisdictions and languages, add in the complexity of joint ventures, patent laws, sub-contracting and outsourcing research to CROs and it is hardly surprising that some FDA and EMEA (European Medicines Agency) submissions were traditionally delivered not by the box load but by the truck load.

Going Beyond Table Stakes

In order to streamline the submission process, the FDA has introduced eCTDs. The eCTD standard - which will soon evolve to RPS (Regulated Product Submission) - is an

interface between industry and the agency for transferring regulatory information while at the same time taking into consideration the facilitation of the creation, review, lifecycle management and archival of the electronic submission.

The highly collaborative and fractured nature of the research and development process means that many of the original source documents that make up eCTD submissions need to be manually reworked. The rework stems from deficiencies inherent in Microsoft Word or the rendering process itself, particularly the inability to retain key navigation information during conversion to PDF. This kind of manual rework is time consuming, prone to error and, not surprisingly, very expensive.

In addition, the documents for an Investigational New Drug Application (IND) or New Drug Application (NDA) submission are always “in play” – constantly under review, endlessly annotated and eternally being “improved.” However, these improvements must not corrupt the perfection of the submission. Too often, post-production re-rendering is where critical errors are made or repeated.

The end goal in preparing an NDA submission is the generation of high-quality, submission-compliant PDF documents that accurately and precisely represent the source data. Achieving this goal can be a time consuming and highly iterative process, especially without the right technology in place.

Submission Ready PDFs – A Proven ROI

Every pharmaceutical and life sciences organization has some submission process already in place. But, when every day is critical, having leading-edge document management technologies coupled with collaborative document transformation tools is a significant competitive advantage. The effective implementation of these technologies can significantly accelerate submission lifecycles, which contributes directly to the bottom line.

Even companies not required to make eCTD-compliant submissions are seeing the advantages of an electronic workflow in accelerating time to market. They are finding ways to leverage the technology and transform eCTD into suitable printed CTD. The

European Union has mandated that all 27 member countries be ready to accept electronic submissions by 2009.

Robust PDF rendering forms the backbone of many document management workflows and is the lifeblood that flows through the entire eCTD submission lifecycle. By creating higher quality renditions, quality assurance churn can be reduced to only minutes per document. This is a significant process acceleration over traditional QA cycles – searching for missing, broken and invalid hyperlinks – that usually takes hours to complete. Consider that the manual process of document review and editing can typically take 120 minutes per document. Automating the document transformation process can reduce this time to 10 minutes. For a company that submits just 100 documents per week, automating the process can save 183 man-hours per week or $572,000 per year (based on a salary of $60 per hour).

The cost savings, projected over submissions running into the hundreds of thousands or even millions of pages, have proven to be enormous.

Steps for Choosing the Right Software

Submission-ready PDFs are infinitely flexible and contain an almost limitless set of features. These PDF outputs can be readily equipped with essential elements like access control, standardized hyperlink styles, embedded fonts, comprehensive tables of contents, audit history and bookmark structures. These PDF documents are also flexible and scalable at every stage of the submission lifecycle, particularly important given the FDA's increasingly assertive use of post-marketing "risk minimization action plans" (RiskMAPs).

In order to achieve the benefits outlined in this article, organizations should keep the following tips in mind when selecting their document conversion provider:

- **Quality is Key** – pick an application that focuses on document rendering quality. The better the quality, the less amount of time required to review and update each document.

- **Ease of Integration** – the last thing you want is to write custom code in order to introduce a document rendering technology into your infrastructure. Make sure to choose an application that employs a design philosophy of stable, open protocols and standards such as XML and Web services, which can fit right into your infrastructure.

- **Natural Workflow** – if you want employees to adopt the technology, it needs to seamlessly fit into the overall document workflow of the organization. Eliminate any steep learning curves and the rate of adoption will soar.

- **Compliance Ready** – look for a document conversion application that supports your regulatory compliant strategy. Not all applications are created equal. Ensure that the application has a successful history in life sciences – specifically for regulatory submissions.

- **Document Transformation** – it's not enough to bring in a simple PDF conversion tool and expect all your needs will be met. Look for applications that have the ability to handle all of your document transformation needs, including; document assembly, OCR text recognition as well as document conversion. Why buy 3 or more applications when one will do?

- **Scalability and Reliability** – the demands of submissions are high. Fluctuations in volumes coupled with the critical nature of speed to market dictates that you look for a robust application that can easily scale to meet your needs while reliably getting the job done with a high degree of certainty and fidelity.

A robust regulatory publishing infrastructure is designed to be a foundation for growth for life sciences organizations. This critical infrastructure takes advantage of existing investments in skills and technology to achieve document management efficiencies that support the critical work being conducted on behalf of the population – and corporate shareholders. A small investment in the right technology choice can lead to cost-savings, rapid ROI and faster time to market.

About the Author

Scott Mackey is the director of product management for Adlib Software. He has spent the last 10 years working with leading companies in the life sciences industry to build document rendering solutions optimally tailored to meet the stringent needs of this community. Mackey continues to work with Adlib's life sciences partners to design better tools that will eventually lead to more efficiencies and better solutions throughout the enterprise document management space. Scott Mackey can be contacted for further comments by calling him at +1.905.631.28785 ext.231 or email: smackey@adlibsoftware.com.