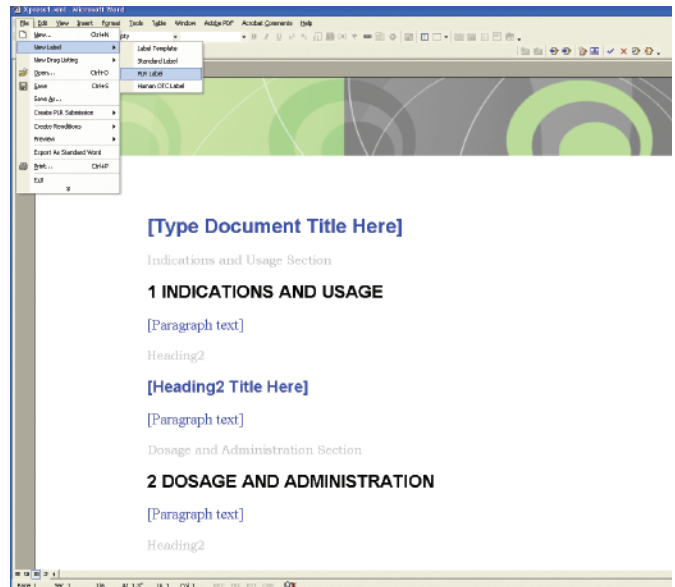


# PAR PHARMACEUTICAL EMBRACES XML FOR SPL AND DYNAMIC PUBLISHING

**A Strong XML Strategy Built on Quark® XML Author™ Allows Anyone on Par's Team to Create FDA-compliant SPL Submissions using Microsoft Word®**

In 2005, Par Pharmaceutical faced the challenge of complying with a Food & Drug Administration (FDA) ruling that required drug product labels be submitted in XML. By mandating that pharmaceutical companies adopt XML, the FDA's ruling was disruptive, adding cost and complexity to the process of bringing products to market. In response to the ruling, Par, a developer and manufacturer of generic and proprietary specialty drugs, turned to Quark for an in-house XML authoring solution that allows the team to achieve compliance quickly, easily, and cost-effectively.



Beginning with the first SPL ruling, Par began leveraging the familiar and easy-to-use Microsoft Word interface of Quark XML Author. Now Par creates and electronically submits compliant, XML-based labeling, drug registration, drug listing, and labeler code registrations to the FDA, and anticipates even more XML requirements from the FDA in the future. With Quark XML Author, Par is also able to plan for and achieve savings by using XML to automate downstream processes, such as producing labeling and packaging, which are currently both labor-intensive and error-prone.

## Structured Product Labeling (SPL) Rulings

In early 2004, the FDA passed the Structured Product Labeling (SPL) ruling requiring that prescription drug manufacturers submit specific and detailed information about their products as a part of the drug approval process. The ruling mandates that the SPL content be submitted in XML, a standard for structuring documents.

At the time, the FDA accepted both electronic and hardcopy submissions in Microsoft Word and PDF. The content was then converted into XML and published as product labels and patient information forms, as well as published online for physicians and the general public to access. The FDA chose XML as the standard for product labeling submissions because XML content can be easily managed, reused and automated.

### GOING PAPERLESS WITH XML

Pharmaceutical companies can lose up to \$1 million dollars in revenue each day it takes to bring a drug to market. The FDA requirements for structured submissions and the potential revenue opportunity have created a compelling reason for pharmaceutical companies to go paperless with XML. Once implemented, the right XML solution will be easy to use, cost-effective, and create a number of opportunities to streamline and automate a pharmaceutical company's publishing processes.

As part of the evolution of SPL rulings, the FDA approved the Physicians Labeling Rule (PLR), which requires that content for product labels must not only be submitted in XML, but also in a specific format and layout. And most recently, the FDA issued SPL R4, a revision to SPL that mandates that starting June 1, 2009, all product label content must be submitted by pharmaceutical companies electronically in XML.

Although these efforts by the FDA make it much easier for doctors and consumers to gain access to accurate drug information quickly, they have had a significant impact on pharmaceutical companies. Now drug manufacturers are forced to understand a complicated authoring language – XML – as well as submit product details in a very specific format.

### Becoming Compliant: Outsourcing versus In-House XML

There are two common options for meeting the SPL mandate: convert Microsoft Word and PDF documents to XML in-house, or outsource the conversion.

Both options can be daunting. First, very few people in charge of submitting product details are familiar with XML in general or the specific XML coding of SPL. Outsourcing takes the burden of learning XML off the product and marketing teams. On the other hand, the team loses control of their information, conversion services are expensive, and there is a high potential for client conflict at the vendor.

**“Quark XML Author’s ease-of-use and simplicity enabled us to initially become SPL compliant in just three days. As the SPL standard evolved it has helped us cost-effectively maintain compliance and prepare for future requirements.”**

**— Michele Cobham, Submissions Manager,  
Regulatory Affairs, Par Pharmaceutical.**

Par considered outsourcing conversion of their SPL labels, but ultimately opted against it. Michele Cobham, submissions manager for regulatory affairs at Par, leads the effort to ensure Par is SPL compliant. She said, “At the time of the original SPL initiative there were significant issues around outsourcing XML conversion. Cost, first-to-file labeling, and possible conflicts with other clients at the conversion houses were enough to warrant the creation of labels to be kept within Par.”

Rejecting the option to outsource, Cobham and her team tested several solutions for converting its initial labels into XML, but many of the tools proved to be too complicated. Along the way, however, she discovered Quark XML Author, a key component of Quark Dynamic Publishing Solution that allows users to create XML content directly in Microsoft Word. Par tested – and soon adopted – Quark XML Author with Quark’s SPL Accelerator to bring the creation of SPL-compliant labels in-house.

**ABOUT MICHELE COBHAM,  
PAR'S RESIDENT SPL/XML EXPERT**

With 14 years of pharmaceutical experience both in a branded and generic environment, Michele Cobham has expert knowledge of the regulatory affairs and compliance challenges that pharmaceutical companies face. Currently, as the submissions manager on the regulatory affairs team at Par Pharmaceutical, her focus is in the areas of electronic document management systems, life-cycle management, XML/SPL initiatives, and the electronic Common Technical Document (eCTD). She is a member of the Drug Information Association (DIA), Regulatory Affairs Professional Society (RAPS), and the HL7 SPL Working Group with membership on the Generic Sub-Team and the Process Communications Forum.

"Par Pharmaceuticals recognized immediately that XML would be a driving force in FDA regulations going forward, and that a simple yet effective solution would be important for long-term success," said Richard Brandt, vice president of life sciences for Quark. "Par is a leader in XML adoption for SPL compliance and has taken significant steps to align many of their business processes around a familiar authoring environment for easy reuse."

**Quark XML Author**

Quark XML Author is an add-in to Microsoft Word that lets anyone create XML documents — without seeing tags, being constrained to boxes, or being aware of the technical complexities associated with XML. Quark XML Author also ensures that the content an author creates is constantly validated against the XML standard, eliminating the need to rework content at a later time.

The Quark SPL Accelerator, which Quark developed specifically to address FDA requirements for the SPL format, is a commercial, out-of-the-box solution for producing SPL submissions using Quark XML Author and Microsoft Word. The Quark SPL Accelerator converts Word content into valid and compliant SPL files. Because the solution is based on Microsoft Word, the Quark SPL Accelerator helps companies implement an XML-based process with minimal business disruption.

**"Having an XML authoring environment in a familiar application was crucial because we are not only used to, but adept at working with Microsoft Word. It was a simple approach that we could embrace quickly."**

— Michele Cobham

The fact that the authoring environment in Quark XML Author is Microsoft Word was very important to Cobham's decision to go with Quark. "Microsoft Word is the standard word processor within Par. Having an XML authoring environment in a familiar application was crucial because we are not only used to, but adept at working with Microsoft Word. It was a simple approach that we could embrace quickly."

Because Quark XML Author with Quark SPL Accelerator requires minimal training, Cobham and her team were able to implement Quark XML Author and begin submitting compliant, XML-based product labels to the FDA within three days. The quick turnaround time saved the company time in bringing drugs to market and improved revenue potential while allowing Par to maintain control over their intellectual property.

"We have a great alliance with Quark and its XML-based tools. Quark XML Author is definitely a tool that makes my job easier while allowing our content to be compliant for the needs of the FDA," said Cobham.

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### Well-Positioned for Additional XML-based Initiatives

The benefits of implementing an easy-to-use XML authoring solution in-house do not end with compliance with the FDA's SPL ruling. Cobham believes that it is inevitable that FDA will continue to move toward full XML authoring requirements.

“Submissions have already moved to an XML-based system. Clinical as well as Chemistry, Manufacturing and Controls (CMC) initiatives are being announced. Soon stability reports and clinical studies will be authored using an XML authoring tool much like what we are currently using for labeling. The Regulated Product Submissions (RPS) initiative will be an XML-based initiative and will be the next step in electronic submissions,” she said.

As the SPL and PLR mandates continue to evolve, is it clear that there will be many more XML-based initiatives coming from the FDA and other federally regulated arenas. Cobham suggests that initiatives around advertising, marketing, and Internet-based applications will all require XML. Because Quark XML Author with Quark SPL Accelerator provides a foundation built on Microsoft Word, Par has been able to go from what was once managing the conversion of Microsoft Word and PDF content to XML, to creating electronic submissions in XML and is ready for a future built on XML content

*If you want to learn more about this particular success story or about how Quark's products and solutions might benefit your business, please visit [quark.com](http://quark.com) or contact us by email or phone using the contact details provided below. If you are interested in having your own success story published by Quark, please contact Quark's PR team at [pr@quark.com](mailto:pr@quark.com).*

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