

Pharmaceutical Regulation

Fulfill SPL and PIM Requirements with Quark® XML Author™ for Microsoft® Word

BENEFITS

Easily create compliant XML

Increase user acceptance and reduce the learning curve with an out-of-the-box solution designed specifically for use with the Microsoft Office Suite. The solution adds XML capabilities to Microsoft Word, hiding XML complexities from users while letting them gain the benefits of XML authoring.

Collaborate effectively, speed time-to-market

Let multiple authors work on different components of documents at the same time, reducing project timelines. Bring subject matter experts into the publishing process so that they can contribute content directly.

Publish documents automatically

Combine Quark XML Author with Quark Publishing System® to automatically assemble information components and publish to print, Web, and other formats.

Gain the benefits of XML publishing across your organization

Create a collaborative publishing process to connect contributors across your organization through a single publishing system.

The Technical Challenges of SPL and PIM Requirements

Companies that make pharmaceuticals face increasing regulatory requirements for XML-based information, such as Structured Product Labeling (SPL) and Product Information Management (PIM). But transitioning existing content to XML and creating new content in XML to comply with these regulations pose significant challenges:

1. Outsourcing the conversion of existing materials gives external parties access to your information, which can create conflicts of interest, especially for first-to-file submissions
2. Shifting to an XML-based authoring approach in-house requires staff to learn technical XML tools and long, expensive implementations of new systems

Yet transitioning to XML as the foundation of your content can actually take costs out of the publishing process and help you better meet XML-based regulatory requirements across all of your published information.

Now you can overcome the technical complexities and expense of XML implementations and adopt a cost-effective XML strategy to meet regulatory requirements while reaping the subsequent benefits of automated publishing. The solution is Quark XML Author for Microsoft Word.

Easily Develop Compliant XML and Meet New Regulations

While XML implementation has traditionally meant adopting proprietary and complex XML editing tools, Quark offers a simpler way. Using Quark XML Author for Microsoft Word, an add-on to Word, your authors can easily create compliant XML content in the familiar Word environment.

By authoring structured XML content in Word, you can easily meet regulatory requirements for SPL and PIM and reuse your content in multiple documents, automatically assemble it into publications, and automatically publish it to multiple types of media — with minimal training and disruption.

overall publishing costs. Because Quark XML Author opens up XML publishing to the general Word user, you can extend XML publishing across your organization, gaining information

quality improvements, cross-media capabilities, and cost reductions while easily meeting new XML-based regulations as they are introduced.

Once implemented, an XML-based solution accessible to all of your Word users will be an easy to use, cost-effective tool that creates many opportunities to streamline and automate your publishing process.

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

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

Not only can you easily meet regulatory requirements, but by authoring content in XML you can also improve information accuracy, speed up your publishing process, and reduce



Structured Product Labeling (SPL)

The Quark SPL Accelerator for Quark XML Author is a commercial, out-of-the-box solution based on Microsoft Word that helps pharmaceutical companies, over-the-counter manufacturers, animal medicine manufacturers, and biologic manufacturers easily meet the U.S. Food and Drug Administration's latest SPL requirements with minimal disruption to your existing process.

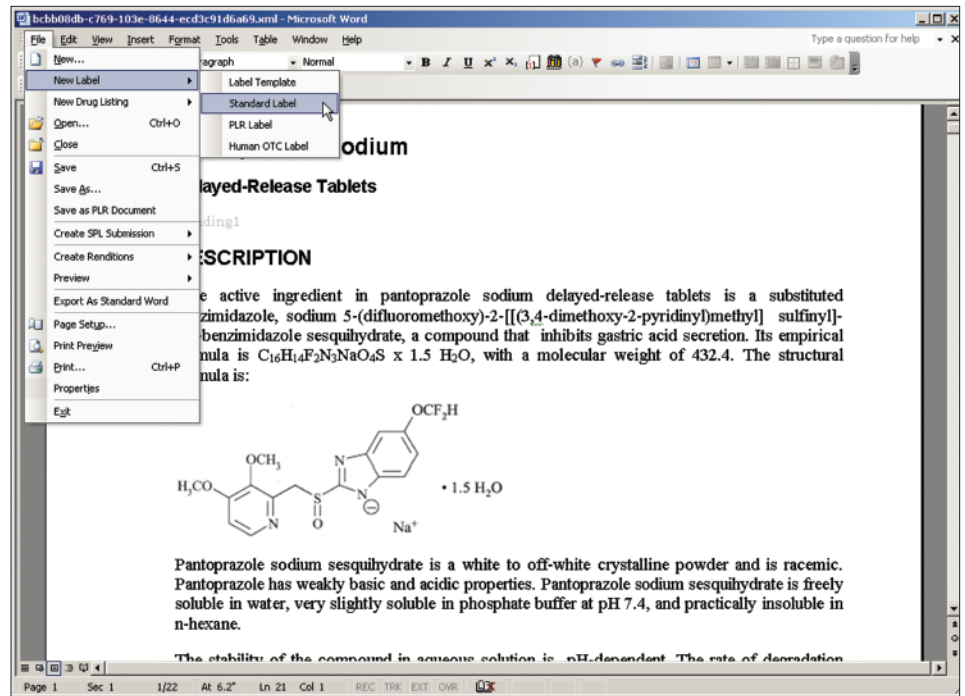
The Quark SPL Accelerator converts Word content into valid and compliant SPL files. Because the solution is based on Microsoft Word, the Quark SPL Accelerator helps companies implement an XML-based process with minimal business disruption.

Product Information Management (PIM)

To help life sciences companies meet the PIM requirements of the European Medicines Agency (EMA), Quark partners with leading systems integrators such as Glemser Technologies, which offers a global solution for labeling. Quark XML Author for Microsoft Word can play a key role in PIM implementations by making it easy for authors to create complete and valid content.

Why XML?

XML offers two significant efficiencies to the publishing process. First, XML provides the consistent document format that automated publishing requires. While Quark Publishing System can import content in other formats, such as native Word documents, inconsistencies in those documents may require correction before automated processing. But with an XML front end like Quark XML Author, Word users can create consistent documents that flow through without intervention.



Quark's SPL Accelerator for Word supports all FDA SPL submission types. This screen shot shows options for the content of labeling and the drug listing templates.

A second advantage of XML is that it frees authors from spending time on page layout and design. By focusing on creating content and leaving the document formatting to downstream processes, authors can be twice as productive.

Quark XML Author

Quark XML Author is an add-in to Microsoft Word that lets authors create XML without learning XML's technical complexity.

It remains invisible until you try to create or edit an XML file. At that point, Quark XML Author modifies Word's user interface for XML editing. While many Word functions operate normally, others change in subtle ways to ensure that you are creating correct XML.

Microsoft looks to partners such as Quark to enhance Word's built-in XML capabilities. Quark XML Author allows users to create XML text and tables directly in XML, using either an industry standard such as SPL or a custom tag set.

Why Quark?

- Quark XML Author meets the needs of IT staff for XML document quality, while giving end users simple usability to create intelligent XML documents. In contrast to niche applications, Quark XML Author allows users to create XML documents that conform to any schema or DTD.
- Only Quark offers the combination of easy XML authoring in Microsoft Word and, through Quark Publishing System, automated publishing of richly-designed documents to print, Web, and digital formats.
- Quark is a Microsoft Certified Gold Partner and member of the Office 14 Developer Advisory Council.

For more information about Quark XML Author, visit www.quark.com.

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