

Meet SPL Requirements through Easy XML Authoring

Quark SPL Accelerator for Quark XML Author

BENEFITS

- ▶ Meets all SPL authoring needs through a single solution
- ▶ Supports creating XML documents with Microsoft® Word — the primary business tool for millions of knowledge workers worldwide
- ▶ Requires little training and no understanding of the technical aspects of XML
- ▶ Automatically updates R3 documents to R4 compliance
- ▶ Easily transfers content from existing Word documents to the SPL XML format
- ▶ Provides a user-friendly interface for managing drug and product listing data
- ▶ Validates document content prior to FDA submission through a rules engine
- ▶ Reduces business disruption normally associated with adoption of new technology

Meeting SPL Requirements

In order to meet the U.S. Food and Drug Administration's (FDA's) requirements for structured product labeling (SPL), pharmaceutical companies, over-the-counter manufacturers, animal medicine manufacturers, and biologic manufacturers must implement XML-based systems.

These systems must meet the FDA's requirements for both Content of Labeling and Product Listing Data as well as the electronic version of drug listing paper forms 2656, 2657, and 2658.

Quark has been at the forefront of providing SPL submission solutions since the inception of the FDA standard in 2004 and continues as a recognized leader in life-sciences publishing.

As you evaluate your options to meet the FDA's SPL requirements, you must consider the disruption caused by introducing new processes and technology, costs of available solutions, and the flexibility of your preferred option to evolve in conjunction with future FDA requirements.

Quark® SPL Accelerator for Quark XML Author helps you quickly meet SPL requirements, ensures easy transitions to meet evolving FDA requirements, and extends the benefits of your SPL solution to provide the benefits of XML authoring across your business.

Easy XML Authoring for SPL Compliance

The Quark SPL Accelerator for Quark XML Author is a commercial, out-of-the-box solution for producing SPL submissions using Microsoft Word. You can use Word as you normally do. The Accelerator converts Word content to create valid and compliant SPL files.

Because the solution is based on Word, the Quark SPL Accelerator helps you implement an XML-based process with minimal disruption — it requires little training and no understanding of the technical aspects of XML.

In addition, because the Quark SPL Accelerator provides a flexible foundation built on Microsoft Word, it reduces the amount of effort required to implement subsequent changes necessary to meet evolving FDA requirements.

Quark's SPL solution supports all submission types and requirements, including the following:

- Bulk Ingredient
- Establishment Registration
- Human OTC Drug Label
- Human Prescription Drug Label
- License Blood Intermediates/Paste Label
- Licensed Vaccine Bulk Intermediate Label
- No Change Notification
- Non-Standardized Allergenic Label
- NDC Labeler Code Request
- OTC Animal Drug Label
- OTC Medicated Article Animal Drug Label Types A, B, and C
- Out of Business Notification
- Prescription Animal Drug Label
- Vaccine Label
- VFD Medicated Article Animal Drug Label Types A, B, and C



About Quark XML Author

Quark XML Author is an add-in to Microsoft Word that lets anyone easily create XML documents with no knowledge of XML and little or no training. In comparison, the specialized, proprietary tools of the past:

- Require a significant amount of technical training and expertise
- Limit XML authoring to a small cadre of experts
- Or inhibit XML adoption altogether

Quark XML Author is the next generation of XML authoring tools that:

- Empowers knowledge workers using Microsoft Word to create user-defined XML
- Enables enterprise-wide adoption of XML
- Allows organizations to protect and manage their valuable content assets and streamline their business processes

Integration with Content Management Systems

Optional adapters are available to integrate the solution into content management systems (CMS) such as Microsoft SharePoint®, Documentum®, and OpenText® Enterprise Publisher.

Integration with a CMS provides the benefits of version control and workflow along with the added benefit of content reuse. Content reuse is particularly beneficial when managing establishment registrations for multiple products.

Beyond the Basics

In addition to the desktop version, Quark and its partners provide services to customize the solution to suit organizations' individual needs. Quark also provides annual maintenance and support services to work with client teams on training, upgrading to evolving SPL standards, and submission resolution issues.

Extending the Benefits of XML

The Quark SPL Accelerator comes with Quark's expertise as a global leader in publishing tech-

nology. We have the domain knowledge and tools to provide you with the most advanced solution available to help you extend your SPL content into downstream applications and departments, such as carton layouts, print publishing, marketing communications, and medical information.

Extending the benefits of XML helps you achieve additional benefits in business compliance, information accuracy, and improved productivity across your organization.

For more information about the Quark SPL Accelerator, visit www.quark.com.

North America
Quark Inc.
1800 Grant Street
Denver, CO 80203
solutions@quark.com
+1.800.676.4575
+1.303.894.8888

Europe
Quark Media House Sàrl
Rue Du Monruz 2
2000 Neuchâtel
Switzerland
solutionseu@quark.com
00800 1787 8275
+41 (32) 720 1414

Asia
Quark India Pvt Ltd.
A 45 Industrial Area
Phase VIII B Mohali
160059
Punjab, India
solutionsasia@quark.com
+91.172.2299.131

Japan
Quark Japan K.K.
West 248 bldg.
2-4-8 Ebisu-nishi
Shibuya-ku, Tokyo
150-0021 Japan
solutionsjapan@quark.com
+81.3.3476.9440

