

Fast, Compliant Regulatory Submissions

With Quark® XML Author™ for Microsoft® Word

BENEFITS

Speed content creation and document assembly by up to 25%

Create structured XML content in Microsoft Word; speed up the eCTD submission process by automatically assembling reusable content components into documents

Reduce cost for content creation and document assembly by up to 30%

Streamline the content creation, review, and FDA submission processes; improve the downstream publishing process

Ensure regulatory compliance

- Develop a structured document template library that provides templates for each portion of the eCTD
- Automatically notify authors when content does not comply with template guidelines
- Facilitate the use of proper terms within documents and enable authors to locate and reference external sources through metadata management
- Automatically merge content created by authors using various data sources, eliminating manual copying/pasting or retyping
- Avoid broken inter-document hyperlinks in the eCTD assembly process by leveraging the ability to automatically update external references

The Costly and Arduous Path to New Drug Acceptance

At a cost of nearly \$1 billion over 10 to 15 years for a single drug, it's not surprising that only about 25 new drugs successfully complete the long and arduous path to market every year.

And with a potential loss of \$1 million every day a new drug does not go on the market, pharmaceutical companies are under high pressure to tame the high cost of developing new, innovative drugs and clear the U.S. Food and Drug Administration regulations that are the key to market introduction.

To reduce time-to-market and the cost of the new drug approval process, pharmaceutical companies must:

- Shorten internal and external documentation and approval processes
- Streamline content and regulatory review processes
- Simplify the process of assembling hundreds of thousands of pages into a "package" for submission to regulatory authorities
- Simplify the management of content for the eCTD

The solution to cutting costs and time-to-market is dynamic publishing.

Create Fast, Accurate Content for Regulatory Submissions

Quark's dynamic publishing software provides a new approach for developing fast, compliant regulatory submissions.

Using Quark XML Author, with little to no training anyone can create structured, reusable XML

content in Microsoft Word that can be assembled and published following eCTD submission guidelines. This speeds up the entire submission process, delivers more accurate content, and can contribute to the faster introduction of new drugs on the market.

Our set of software tools:

- Enables reuse of content through the creation of structured XML content components using Microsoft Word
- Enables content referencing and automated content updates when the source content changes by integrating documents with existing business systems and data sources

- Automates content integration from data sources such as databases and other corporate repositories by automatically merging that content with authored content

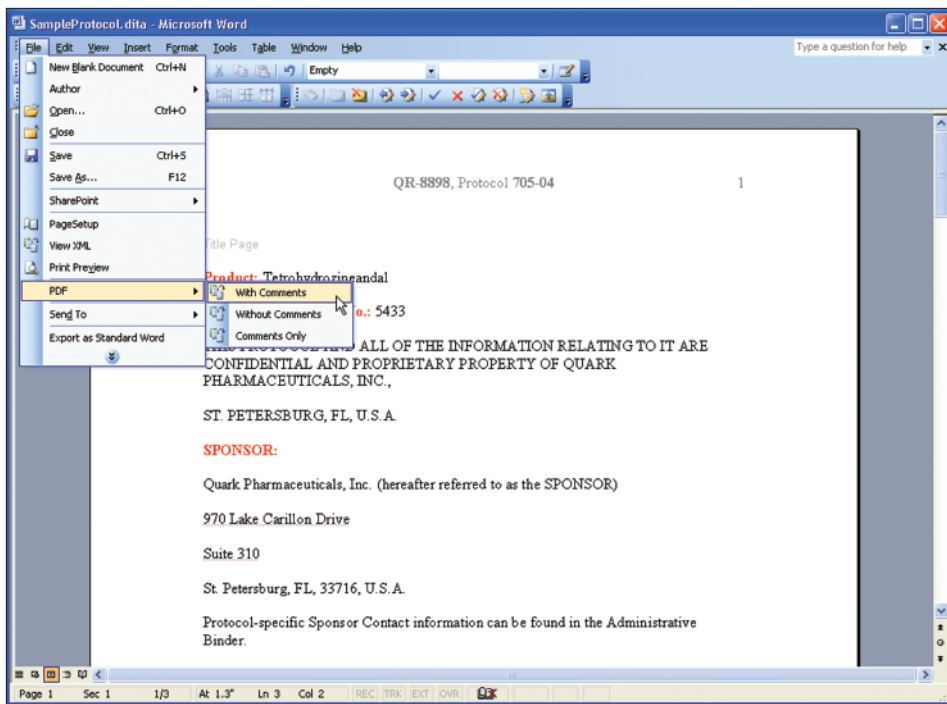
- Simplifies the process of assembling hundreds

of thousands of pages into submission packages by automating routine tasks such as template and metadata management, enforcement of authoring formats, and evaluation of regulatory compliance

- Simplifies the creation of PDF documents for use in the eCTD submissions process

"In order to bring new drugs to market as quickly as possible, pharmaceutical companies need to streamline the creation, assembly, review, and submission process for new and generic drugs."

Richard Brandt, Vice President,
Life Science Solutions, Quark



Quark XML Author presents the user with multiple output formats in the Word environment, including the ability to include or exclude reviewers' comments.

A Dynamic Regulatory Submission Process Using Structured XML Content

Step 1: Content Creation

Author consistently structured content with pre-defined templates using Quark XML Author for Microsoft Word. Content creators work in an environment they know and understand, while at the same time creating consistently structured content. Because Quark XML Author guides authors to create perfectly consistent content, downstream processes for assembling and publishing the content can be fully automated.

Step 2: Content Management

Quark XML Author can be integrated with a content repository such as EMC® Documentum®, Microsoft SharePoint®, and IBM® FileNet® Content Manager. Authors use templates to ensure that documents are consistently built (including metadata) and formatted (structured), significantly improving searching and content reuse.

Step 3: FDA Submission

Once documents are prepared and ready for inclusion in a submission package, package assembly begins in conjunction with an eCTD assembly tool. The structure, format and metadata within the individual submission documents provided by Quark XML Author facilitate document assembly and automatic resolution of cross references.

The system consists of:

- Quark XML Author, an add-in to Microsoft Word that lets anyone easily create XML documents with no knowledge of XML and little or no training. Quark XML Author leads the next generation of XML authoring tools, helping organizations make XML authoring widely available so they can reap the improvements in productivity and information quality that XML delivers through its role in dynamic publishing systems.
- Quark XML Author content management adapters for EMC Documentum, Microsoft SharePoint, and IBM FileNet Content Manager
- Optional components include QuarkXPress®, Quark Publishing System®, and QuarkXPress Server for a complete, end-to-end publishing solution

Why Quark XML Author?

Only Quark offers:

- A new approach to automated dynamic publishing using Microsoft Word together with Quark's industry-standard publishing technologies. Using Microsoft Word as the content creation tool:
 - Is the easiest, most familiar way to create structured XML
 - Significantly reduces training costs
 - Minimizes process disruption
 - Leverages existing investments in tools and processes
- An end-to-end publishing system, from content creation through integration with leading content management systems, to automated multichannel publishing
- Software and technology that adapt to your existing business systems and processes so you can create a publishing solution that meets your individual needs, unlike plug-and-play solutions that require you to adapt your systems and process to meet their requirements

For more information on creating fast, compliant eCTD submissions with Quark XML Author, visit www.quark.com.

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