



Client: World Leading Pharmaceutical Company
Partner: Glemser
Use Case: Documenting Pharmaceutical Test Specifications & Analytical Methods
Users: 500+
Country: Global
Goal Regulatory Compliance



Leading Pharmaceutical Company Improves Legal and Regulatory Compliance with Structured, Reusable Content Authoring

This organization researches, develops, produces and markets pharmaceuticals around the world.



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Challenge

Creating, managing and publishing test specifications and analytical procedures for pharmaceutical ingredients requires the highest standards for security and consistency. These processes, which are key not only to document management but also to demonstrating regulatory compliance and shortening market launch times, must also be efficient.

Solution

The company uses **Quark XML Author**, part of **Quark Publishing Platform (QPP)**, integrated with xmContent from Glemser. Different departments can write structured XML content in the familiar Microsoft Word environment, incorporate it into their workflows and reuse it at any time without having to know XML.

Results

- Ability to create, manage and publish content in line with regulatory requirements and legal guidelines for the submission of approval documents for pharmaceuticals
- Easy adoption and use because of familiar Microsoft Word environment
- Content saved centrally as text blocks available for reuse at any time, regardless of media format
- Fast and cost-effective workflows

With XML-based document management, format requirements can be implemented easily for the submission of documents for approval, so the company decided to replace its existing RDBMS as part of its GSpecS 9 (Global Test Specifications) project. It awarded a contract to Glemser for the expansion and implementation of its XML-based system for the creation and management of test specifications and analytical procedures.

xmContent from Glemser is flexible, adaptable and can therefore connect to different XML authoring tools. After an extensive analysis of eight different XML editors, looking at user-friendliness, error-handling, core and add-on functions, and configuration and expansion options for future viability, the pharmaceutical company selected Quark XML Author, a Microsoft Word plugin that allows writers to develop structured XML in this familiar word-processing environment without requiring XML expertise. The Word-based authoring environment, combined with QPP's content repository and workflow engine, provides an end-to-end content automation solution to help meet pharmaceutical industry use cases.

Glemser integrated and configured Quark XML Author into xmContent to meet the company's requirements on the basis of the BusDocs standard. The Quark XML authoring tool can be configured so that users only have access to the functions they actually need.

Five hundred employees within the company use Quark XML Author to create XML-based documents via Microsoft Word, with the XML code invisible in the background – no tags, no restriction to frames. Because XML expertise isn't required, training to use the solution is minimal, and once configured and adapted to a company's requirements, it is easy to use.

Used together with other system components like xmRender, Quark XML Author allows regulatory formatting requirements to be implemented. The content is saved as structured text blocks in a central content repository and can be reused at any time for publication with different formatting requirements.

The global use of Quark XML Author also has translation advantages because Glemser can connect Quark XML Author to a translation memory system.



If a quark – in science – is the basis for all matter, then Quark – the company – is the basis for all content. The company revolutionized desktop publishing and today provides content design, automation and intelligence software for end-to-end content lifecycle management. Customers worldwide rely on Quark to modernize their content ecosystems so they can create complex print and digital layouts, automate omnichannel publishing of mission-critical documents, and analyze production and engagement insights for the greatest return on their content investments.

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