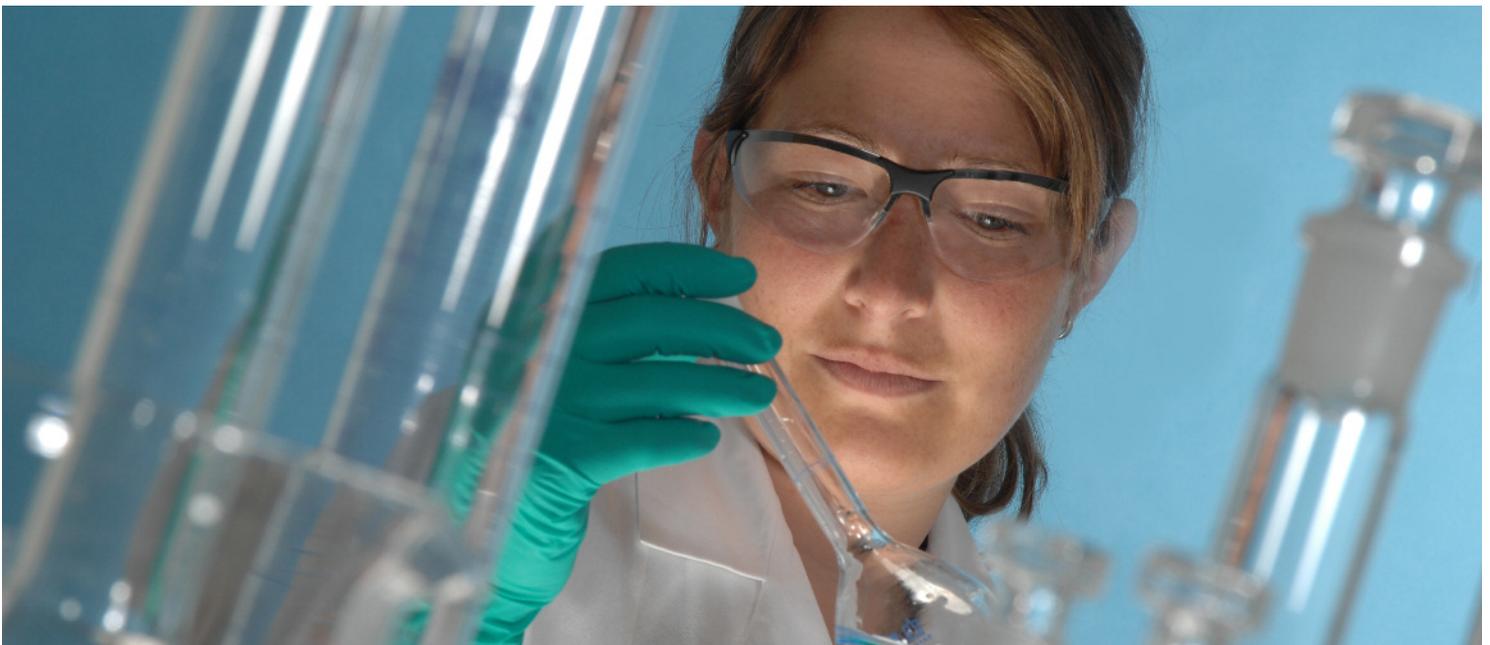QUARK
ENTERPRISE
SOLUTIONS

BOEHRINGER INGELHEIM RELIES ON XML SOLUTION FROM QUARK TO CREATE AND MANAGE LEGALLY COMPLIANT PHARMACEUTICAL DOCUMENTS

500 USERS AT BOEHRINGER INGELHEIM COUNT ON QUARK XML AUTHOR FOR ELECTRONIC COMPILATION AND PUBLICATION OF TEST SPECIFICATIONS AND ANALYTICAL METHODS FOR PHARMACEUTICALS AND ACTIVE INGREDIENTS.

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Boehringer Ingelheim researches, develops, produces, and markets pharmaceuticals around the world, and with 47,400 employees it is one of the top 20 largest pharmaceuticals company in the world.

When creating, managing, and publishing test specifications and analytical methods, the highest standards for security and consistency must be met. In order to satisfy these standards and at the same time increase process speed and efficiency,

Boehringer Ingelheim switched to XML-based document management with Quark XML Author. Thanks to the newly implemented XML authoring software, different departments can create structured XML content directly in the familiar Microsoft Word environment, incorporate it into the workflow, and reuse it at any time, all without any XML knowledge whatsoever. About 20,000 test specifications and analytical methods have already been created at Boehringer Ingelheim with XML Author.

Boehringer Ingelheim

Quark

Boehringer Ingelheim must take the utmost care when compiling documents, as the contents must comply with a variety of legal regulations, such as pharmaceutical legislation, EU directives and internal standards. At the same time, cost-effective document management and short market launch times are critical to the company's success. In order to structure the creation, management, and publication of content to be more secure and cost-effective, Boehringer Ingelheim searched for a new solution for XML authoring that would make it possible to flexibly enter both structured data and free text, depending on the situation, and thereby work quickly and effectively.

New Requirements Require New Tools

With XML-based document management, format requirements can be easily implemented for the submission of approval documents. Boehringer Ingelheim therefore decided to replace its existing RDBMS system x, and as part of its GSpecS 9 (Global Test Specifications) project it awarded the contract to Glemser Technologies 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 very flexible, adaptable, and can therefore connect to different XML editors. Before Boehringer Ingelheim made its decision, the company completed an extensive competitive analysis in which eight different XML editors were compared. The test criteria were user-friendliness, how errors are handled for incorrect entries, the core and add-on functions, and the configuration and expansion options for XML editors and their future viability.

The winner of the competitive analysis was Quark XML Author, the only XML Editor for Microsoft Word that creates permanently valid XML when the data is entered. Quark XML Author is an add-in for Microsoft Word that offers a high-end total solution for creating guideline-compliant documents for the pharmaceutical industry when used together with a content repository and workflow engine. The fact that Quark XML Author uses the Microsoft Word writing environment was very important to the decision made by Boehringer Ingelheim.

Creating XML Without XML Knowledge: Quark

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XML Author Makes It Possible

Glemser completed the integration and configuration of Quark XML Author into their product, xmContent. Quark XML Author was expanded here to meet the requirements of Boehringer Ingelheim on the basis of the busdocs standard. The XML editor can be configured so that the user only has access to those functions that he actually needs. The resulting simplicity for the user is very important.

500 users at Boehringer Ingelheim create valid XML documents directly in Microsoft Word without any XML knowledge whatsoever, similar to how text is entered in Word. The XML code remains invisible to them – no tags, no restriction to frames. No one has to deal with the technical complexity of XML. As a result, the initial training for the team in Quark XML Author requires only a minimum of effort. Configured once and adapted to the company's requirements and XML scheme, the XML editor is easy to use.

Separating Data and Formating – The Key To Success

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 later at any time for publication with different formatting requirements.

What future plans does Boehringer Ingelheim have for XML-

based document management? The global use of Quark XML Author offers a number of advantages for translation as well. Glemser offers the option of connecting Quark XML Author with a translation memory system. Here the already high ROI for the XML solution can be improved once again.

CHALLENGES

- Strong regulatory requirements and legal guidelines for the submission of approval documents for pharmaceutical products

- Extensive database of test specifications, analytical procedures, and pharmaceutical information

- High processing speed is necessary in order to accelerate market launch times and work cost-effectively

SOLUTIONS

- Quark XML Author for Microsoft Word together with xmContent from Glemser

RESULTS

- XML authoring without any XML knowledge in the familiar Microsoft Word user environment

- Content is saved centrally as text blocks and is consistently available for reuse at any time, regardless of media format

- Create, manage, and publish content that adheres with compliance and conforms to guidelines because Quark XML Author can be adapted to any XML scheme whatsoever.

ABOUT QUARK SOFTWARE INC.

Quark's software enables organizations of all sizes to meet customer demand for engaging, relevant communications when, where and how they want them. Our solutions combine the power of XML with flexible layout and design to automate the delivery of customer communications to print, Web, and interactive experiences on the latest digital devices. Financial services firms, manufacturers, and governments around the world rely on Quark solutions to elevate customer communications to new levels, reduce time to market, and lower costs.

To find out more about Quark Enterprise Solutions visit **www.quark.com/enterprise** or contact us at **www.quark.com/contact**

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