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Cimage NovaSoft Solution Manages eProcesses & Documents in Research and Manufacturing at Byk Gulden

Byk Gulden (<http://www.byk-gulden.com>), the pharmaceuticals division of the Altana group, is an international researching pharmaceutical company based in Konstanz, Germany, with over 6,400 employees and 28 subsidiaries worldwide. The company specialises in the field of therapeutics and conducts its own research – an approach which secures the company's excellent world-wide market position achieving sales of more than 1.2 billion euros in 2000.

Byk Gulden constantly reviews its systems and processes in order to maintain its competitiveness. With increasing global competition and stringent regulatory pressures, the company recognises that it is vital to maintain fully validated records and complete

audit trails for its research and manufacturing processes. When applying for new product approvals, a large number of documents must be provided to the drug regulators. In order to manage document workflows within the drug regulatory submission chain and to comply with related guidelines in Europe and the USA, such as FDA 21 CFR Part 11, the company decided to implement an information management solution.

INCREASING WORKFLOW EFFICIENCY AND REGULATORY COMPLIANCE

In 1999 Dr. Ruediger Buchkremer, head of Byk Gulden's Department of Information and Documentation, took charge of the project to find a supplier to provide the workflow and audit functionality required to meet the new challenges that the company was facing. Above all, he wanted to reduce the risk of procedures not complying with regulatory guidelines.



Byk Gulden offices, Konstanz, Germany

Following an intensive evaluation programme and visits to reference sites, the company chose Cimage NovaSoft's solution for the pharmaceutical industry.

Dr. Buchkremer explains: "We were looking for a solution that would enforce regulatory compliance with integrated workflow processes – and meet the stringent requirements for electronic signature as stipulated in 21 CFR Part 11. Cimage NovaSoft was able to provide a solution that could help us achieve our mission-critical goals."

MINIMAL CUSTOMISATION

Cimage NovaSoft's NovaManage solution was based on the company's many years of experience in the pharmaceutical industry, providing customisable data models and user interfaces as well as controlled printing templates pre-configured for the specific requirements and terminology of FDA regulated industries. It could also demonstrate a track record of successful implementations.

According to Dr. Buchkremer: "The degree of customisation required for document management processes with Cimage NovaSoft was minimal. This was a major consideration for us, because it enabled us to implement quickly and at a lower cost. In addition, the standard components of NovaManage such as "logical documents" are used without modification to develop complex applications like the generation of study reports. (In NovaManage, a logical document is a set of files of any type that are grouped together like the chapters of a book). Revision control can be applied at the logical document level, so you have the right version of every component document. The controlled documents of NovaManage are made available in a submission management system for the dossier compilation."

Updating and maintaining information is simplified using electronic mark-up and routing of documentation, thereby ensuring reviews and amendments are streamlined. Because the system enforces compliance, the risk of errors is reduced and compliance costs are controlled.

PROVEN 21 CFR PART 11 COMPLIANCE

Crucially the system verifies that the approvals are valid and that documents are signed by the right people - even when they are being signed simultaneously in different locations. The workflows are handled completely electronically with the electronic signature included. This helps to reduce the time taken to obtain multiple (international) document approvals and has been independently audited for FDA 21 CFR Part 11 compliance.

AHEAD IN THE PHARMACEUTICAL RESEARCH FIELD

Based on an Oracle client-server database environment, installation of the new system commenced in September 1999. Within a year the system was validated and ready to use across a number of departments working within a regulated environment, including some who were accessing information from different countries.

Dr. Buchkremer comments: "Cimage NovaSoft's graphical workflow makes it very easy to use so we were quickly up and running."

Dr. Buchkremer concludes: "Electronic workflow processes are not yet used widely in pharmaceutical research. Cimage NovaSoft's solution addresses our regulatory compliance needs at a time when the industry is just beginning to realise the benefits of digital workflow. It not only makes us more efficient, it really puts us ahead of the field."

LOOKING TO THE FUTURE

The initial Cimage NovaSoft project was completed on time and to schedule. Sibylle Teuchmann (Project Leader) is managing a follow-up project to roll out the new electronic processes more widely in the areas of research and manufacturing. The first phase of the project is a planned upgrade to the latest version of NovaManage for Windows 2000. Also under consideration are improvements to the document review processes (redlining), implementing hyperlinks between individual documents and using NovaManage's web integration facilities for document search and workflow.

CASE STUDY

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