Case Study

Actelion’s Quatro System: MasterControl by Any Other Name Stands for Compliance and Efficiency
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What’s in a name? At Actelion, MasterControl is known as Quatro, which stands for Quality and Training Management Optimized. But to paraphrase Shakespeare, MasterControl by any other name stands for compliance, effectiveness, and efficiency. That much is apparent when comparing Actelion’s experience before and after Quatro’s implementation. In addition, the company is also using MasterControl QAAD, an audit management solution.

Actelion, a biopharmaceutical company based in Allschwil (near Basel), Switzerland, is well-known globally for its innovative products that treat pulmonary conditions and Gaucher disease, a rare genetic disorder stemming from a lack of an enzyme called glucocerebrosidase. Actelion manufactures Tracleer, Veletri, and Ventavis for pulmonary conditions and Zavesca, the first and only oral medication approved for adult patients with Type 1 Gaucher disease.

Actelion complies with numerous regulations and standards, including:

- U.S. Food and Drug Administration (FDA) and European Union (EU) regulations pertaining to Good Manufacturing Practice (GMP);
- Organisation for Economic Cooperation and Development’s Good Laboratory Practice principles;
- European Medicines Agency’s Good Pharmacovigilance Practice guidelines; and
- ICH E6 (Good Clinical Practice) quality standards, which have been endorsed by the FDA, EU, Japan, and other countries.
Old Dual System

Prior to using Quatro, Actelion used two systems—one for quality and another for training—that had to be manually synchronized, according to Rudi Frank, Actelion’s vice president of global quality management.

The dual system’s most basic problem was that it was slow. Tracking had to be done separately by using Excel spreadsheets. Revisions were made manually, requiring a form for tracking and another form for a user’s “wet” signature. Documents and records were stored in a GQM-secured archive.

The old quality system was effective as a global repository, but it did not provide role-based access. It was capable of generating only a few types of reports. Role-based access is critical because it ensures privacy of data by limiting a user’s access only to documents that are pertinent to his or her responsibilities. So without role-based access, the previous quality system was missing an essential functionality.

The old training system’s primary benefit was that it automated training records, as well as the process of notifying employees about their training tasks.

New Quatro System

The company replaced its dual system with Quatro in 2011. Before that, Actelion was already using MasterControl QAAD (since 2005). Quatro integrates MasterControl Documents and MasterControl Training—providing a centralized, web-based platform for Actelion’s quality management system (QMS).

Actelion is a public company (listed in Swiss Stock Exchange) incorporated in 1997. It is a global company with an office in the United States and marketing and sales subsidiaries in 30 countries. It has 2,500 employees worldwide who are using Quatro in various roles. In addition, there are 100 contractors who have been granted access to Quatro. Of the total 2,600 Quatro users, 500 are document editors and another 100 users are responsible for training. Ten employees whose jobs pertain to Good Clinical Practice (GCP) compliance use MasterControl QAAD for audit management. Actelion’s QMS has improved vastly, thanks to Quatro. The biggest advantage is that the company now has a single system for both document and training management.

Rudi Frank said the new system has helped tremendously in his role of overseeing quality and ensuring GMP, GLP, and GCP compliance. “Quatro has helped me especially in streamlining the review and approval process of QS documents and providing me a superb tool for assessing the compliance state of Actelion. For instance, the system’s search capabilities can readily show me the number of overdue QS documents for revision,” he said. Asked about other benefits Quatro provides, he identified the following:
• **Harmonised user interface**: MasterControl provides a harmonised graphical user interface (GUI) that makes the system intuitive, easy to use, and easy to navigate. It provides multiple ways to search and view documents, making it accessible even for casual users.

• **Documents can be created directly in the system**: MasterControl can be integrated with Microsoft Word, making it easy for users to remain in the environment they use in creating documents. Editing and collaborating on documents can be made directly within MasterControl.

• **Electronic signature for author, reviewer, and approver**: With MasterControl, Actelion no longer needs a paper form for signatures. The entire process of writing/creating, reviewing, and approving documents is automated, including appending electronic signatures. MasterControl’s e-signature manifestation includes name, date, time, and meaning of signature. The system’s e-signature capability complies with regulatory requirements (e.g., audit trail requirements).

• **Easier publication process**: MasterControl makes it easier to publish documents, including easier conversion of documents to PDF and customization of cover page. The system controls access to documents, providing a secure publication environment. Before Quatro, publishing was a labor-intensive process that required scanning wet-inked signed documents and uploading them into the system.

• **Automated publication of documents at a chosen date**: MasterControl can be configured to meet a company’s specific publication needs, including automatic publication of certain documents at a chosen date. For example, the system can be configured so when a document reaches its effective date and it moves from the draft vault to the release vault, the document will automatically republish and update the cover page.

• **Creation, assignment, and notification of tasks are all automated**: Automation of tasks is critical in the training management process. With MasterControl, the execution of training, including notification and follow-up of training tasks, dissemination of training materials (documents, audio, video), and testing are all automated. The system offers configurable questionnaire, test, and quiz setup.

• **One System, One Login**: Under the old dual system, access to the document management system was separate from access to the training system. Users needed to log into each system separately. With MasterControl, the two systems are integrated so users need to log in just once to gain access.

**Conclusion**

Actelion is well-known for developing and commercialising innovative treatments for rare genetic conditions and unmet medical needs. The company recently completed Phase III of a clinical research on long-term treatment of patients with pulmonary arterial hypertension, a chronic life-threatening condition.
characterized by abnormally high blood pressure in the arteries between the heart and the lungs of the patient. The study evaluated the efficacy and safety of macitentan, a new dual endothelin receptor antagonist developed from a tailored drug discovery process.

An effective, efficient, and compliant quality management system is vital to Actelion's pursuit of novel treatments. By all accounts, Quatro is meeting the company's QMS needs.

Quatro has improved the overall quality and level of service at Actelion, according to Rudi Frank. He said the company is planning to implement MasterControl CAPA in the near future. Actelion is also looking forward to migrate from MasterControl QAAD to MasterControl Audit, which would allow integration of the audit management process with Quatro.

**About MasterControl Inc.**

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit [www.mastercontrol.com](http://www.mastercontrol.com).