

Actelion Healthcare

Ready for regulatory-compliant e-submissions



Business overview

Actelion Pharmaceuticals Ltd is a biopharmaceutical company based in Allschwil/Basel, Switzerland. The company focuses on the discovery, development, and commercialization of innovative treatments to serve highly unmet medical needs in areas such as cardiovascular, central nervous system, oncology, and immunology, as well as anti-infective indications. Actelion is a public company, listed on the Swiss stock exchange (SIX). It has a global presence through marketing and sales subsidiaries in 28 countries, reaching another 25 countries through partner arrangements, thus covering all key pharmaceutical markets worldwide. Actelion was founded in 1997 and employs more than 2,000 people. In 2008, revenue was CHF 1.47 billion and operating profit was CHF 371.4 million.

Actelion's business momentum is reflected in its growing number of employees—from 5 in 1997 to more than 2,000 in 2009. The company represents the best professional attributes, blending biotech innovation with pharmaceutical discipline and the highest ethical standards.

Challenges

Life sciences organizations are under increasing pressure to ensure that their business operations run smoothly, without interruptions and in compliance with a growing list of regulations. Due to Actelion's enormous growth, the company's existing document management system could not meet all requirements and guidelines, which are considerable in research and development (R&D). "Additionally, document retrieval was rather time consuming," says Peter Herrmann, vice president, head of corporate affairs and compliance and corporate compliance officer at Actelion, summing up the issues. "Up to 2007, we were an organization working mainly with paper submissions to health authorities. Our proprietary document management system could not satisfy the technical challenges that exist around making electronic submissions. Furthermore, we had the dilemma of effective storage of all paper files."

Boosting transparency and enabling electronic submissions

The overall objective was to improve the management of the R&D documents related to a submission, especially to enable electronic submissions and to make sure that Actelion could automatically meet the multitude of applicable legal regulations.

At the beginning of 2007, therefore, the company decided to look for a new system. One of the main goals was to enhance information sharing among geographically dispersed employees. At the same time, the solution had to ensure data integrity and compliance with regulations such as FDA 21 CFR Part 11 and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Also, it had to provide workflow functionality and version control for all business-relevant documents, especially documents of regulatory relevance.

GxP guidelines and FDA 21 CFR Part 11 regulations require that records be protected against unauthorized access and guarantee accuracy and authenticity—including time-stamped audit trails and audit trails that track the execution of electronic signatures. ICH addresses a more economical use of human, animal, and material resources, as well as the elimination of unnecessary delays in the global development and availability of new medicines whilst maintaining safeguards on quality, safety, and efficacy, and regulatory obligations to protect public health.

During the ensuing months, Actelion evaluated the most highly rated vendors of pharma-specific electronic document management systems. Finally, the board responsible chose the FirstDoc product that is integrated with the EMC® Documentum® platform. The board chose the solution because it believed it to best support the challenges of the pharmaceutical industry. “EMC is acknowledged to be a market leader in the pharmaceutical environment. The FirstDoc-EMC solution convinced us, as it not only fulfilled all our selection criteria, but provided a product maturity that Actelion could leverage,” adds Esther O’Driscoll, project manager at Actelion. “It is compliant with all legal regulations that are relevant to us and notably, no customization was necessary.”

“With EMC Documentum, we feel confident in our ability to meet all legal regulations and are able to streamline the whole process—from the creation of a document to its submission to the regulatory authorities. The underlying audit trail and sophisticated access rights ensure the integrity of our documents. Our selection was a good one.”

Peter Herrmann, Vice President, Head of Corporate Affairs and Compliance and Corporate Compliance Officer at Actelion

EMC solution

Implementation started in March 2007, in collaboration with the EMC partner Computer Sciences Corporation (CSC), formerly First Consulting Group (FCG), and was finished by September of the same year. Subsequently, user training started and was gradually expanded over the year. Actelion utilized the super user model, in which certain users in departments are intensively trained. These users are capable of providing expert support to their colleagues in the same department. Advantages of the system are the easy-to-navigate user interface and the use of drop-down menus, which facilitate data entry. The solution went live in January 2008.

EMC Documentum as central environment

Documentum 5.2 was chosen as the underlying infrastructure in order to build multiple solutions and applications on top of a central environment. It is seamlessly integrated with FCG FirstDoc R&D 4.2.1, which has been preconfigured with specific R&D business rules. It organizes submission-related documents in an easy-to-use and secure repository that streamlines submission processes and supports regulatory compliance. The system simplifies processes, shortens the time required to create and approve documents of pre-clinical, clinical, quality, and regulatory types, and addresses regulations like 21 CFR Part 11 and ICH guidelines. Also, FirstDoc provides generic workflows for review, approval, and electronic signature collection when appropriate.

In January 2008, Actelion began using the EMC Documentum platform, which is made up of the following products:

- EMC Documentum Content Server governs the repository—storing, managing, and deploying all types of content including HTML, XML graphics, and more importantly for the Actelion R&D staff, Microsoft Office as well as PDF renditions.
- EMC Documentum Advanced Document Transformation Services makes it easy for Actelion to transform content into PDF. It also provides additional format and metadata extraction support—a necessity for content authors who use advanced features such as template styles, hyperlinks, and URLs in their source documents and wish to preserve these features in their PDF documents.
- EMC Documentum Administrator offers a web-based interface and enables Actelion users to quickly deploy new Documentum environments and to easily manage them on an ongoing basis.

- EMC Documentum Developer Studio provides Actelion with a comprehensive set of tools for developing, customizing, and integrating content applications for desktops, web, and portals.
- EMC Documentum PDF Annotation Services provides Actelion with very useful features for the document approval cycle as it integrates Adobe's review and commenting capabilities. Document integrity and security are preserved throughout mark-up, review, and approval processes.

Users at the worldwide Actelion offices access the system through the web-based FCG interface, built on the EMC Documentum Webtop.

From document creation to submission

The authoring of new single-component documents, such as cover letters and brochures, is based on templates, and is processed by ad-hoc workflows from review to approval, thus streamlining the collaborative approval process.

The creation of documents that form part of a submission requires a complex indexing and classification schema. The classification requirements for all clinical, pre-clinical, quality, and regulatory documents are visually reflected in the FirstDoc interface, and are based on the ICH outline. The schema is based on Documentum DocTypes mechanisms, which help to easily create document classes in order to classify the documents.

Summary

Enhanced information sharing, quality, and integrity

The benefits of a technologically advanced solution for management of R&D documents are many. The scalable and evolving solution offers scope for expansion when required. Actelion intends to make the solution truly global, optimizing sharing of its information across departments. Submissions are now made electronically and appropriate documents are globally accessible.

"We are not processing a huge number of documents. But what is worth more to us is the fact that with EMC Documentum, we have been able to enhance the information sharing process and to accelerate the information flow throughout the whole company and its geographically dispersed sites," says Peter Herrmann. Documents can be appropriately accessed and, another important advantage, the system always provides the most current version. "In the future, information sharing will be improved not only internally, but also with the authorities, for sustaining quality with mutual benefit," adds Esther O'Driscoll.



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