Customer Profile

Content management solutions speed time to market for crucial medications

Business overview
Founded in 1961, Pierre Fabre Laboratories today occupies a privileged position in the French and European pharmaceutical landscape. The second largest independent pharmaceutical laboratory in France (thanks to its Pierre Fabre Medications division), the group is also number one in Europe for pharmacy-distributed dermo-cosmetics, with such well known brands as Klorane, Ducray, Avène, Galénic and René Furterer. The group owes its position to large investments in R&D and the fact that over the last few decades it has put on the market some of the most frequently prescribed proprietary medications for oncology, psychiatry, urology, cardiology, gynecology, and rheumatology. Vinorelbine (Navelbine), for example, is a benchmark treatment for breast cancer and lung cancer launched in 1989 and currently registered in 80 countries around the world, both directly by Pierre Fabre Laboratories and through the intermediary of licensed distributors.

Challenges
In a globalized and increasingly competitive industry, the Pierre Fabre Laboratories have been searching since 1995 for ways to streamline and accelerate the process of submitting files to the AMM (autorisatión de mise sur le marché) to request authorization to put new products on the market.

The AMM constitutes a crucial step in the lifecycle of a new medication, since it determines how the product will be marketed and influences the return on the laboratory’s investment. Any kind of delay in obtaining AMM approval can mean a loss of millions of Euros, compromising research in progress on other products.

Health authorities have charged the AMM with the specific task of assigning medications a therapeutic prescription and posological scheme. Each medication submitted to the AMM for review must be accompanied by files containing the entire set of experimental and analytical data proving the quality, safety, and effectiveness of the proposed medication. These files can contain upwards of 500,000 to 800,000 pages.

Accelerating the processing of AMM files
“These documents are provided by multiple contributors in R&D, and must be compiled and organized according to the extremely strict specifications of the competent health authorities,” says Thierry Adenis, IT director in charge of the Compliance Centers within Pierre Fabre Laboratories. In fact, additions are made to each AMM file during the entire development process of a medication, a process which can last 10 to 15 years from the moment a molecule is identified to the day the product is placed on the market.

Benefits
• Unique reference system and unified searching capabilities
• Rigorous management of user authorizations associated with these documents
• Better traceability
• Productivity gains
In order to improve the productivity of the teams in charge of piloting and organizing AMM files, we needed to ensure the centralization and traceability of documents,” Adenis said. “We therefore decided to deploy a GED project with priority given to R&D; we soon turned to EMC Documentum, which was already the benchmark for document management in the pharmaceutical industry.”

EMC solution
The deployment of the EMC® Documentum® content management platform allowed Pierre Fabre Laboratories to develop two reference systems—one dedicated to international files in the dermo-cosmetic field, and the other (named Ophrys) grouping the individual documents of AMM files. These two reference systems, developed by an internal team, were put into production at the same time in 2003.

Well received by the R&D organization
This initial phase of the project was well received by R&D users, who were in dire need of a tool to streamline document management. During the entire development process of a medication, R&D users continuously add to what over time will become AMM files.

“During the initial phase, we concentrated on creating a nomenclature—in other words, a Documentum reference system filing plan—as well as on document formats. We use a third-party desktop publishing software that sits on Documentum for compiling AMM files,” says Adenis. “In order to assure the acceptance and success of the project, we brought in the end users, and they became genuinely involved, working side by side with the EMC Documentum team.”

Facilitating and reinforcing collaboration with Documentum eRoom
At the end of 2004, in tandem with the deployment of the GED project based on the Documentum platform, several departments expressed the need for a collaboration tool. EMC Documentum eRoom® was chosen following a comparative study.

For over a year now, 90 eRooms have been created and used daily by management, marketing, R&D, and most departments. “We needed to find the proper role for the collaborative element vis-à-vis the GED,” said Adenis, referring to a balance between allowing the creation of eRooms to meet specific needs on the one hand and, on the other, preventing a system in which shared documents would be dispersed throughout collaborative spaces, undermining the effectiveness of the reference systems.

Feedback from users, and a management style attentive to the needs of these users, made it possible to limit the creation of eRooms to specified projects and to needs not being addressed by the reference systems.

Towards genuine knowledge management
Documentum is now used by 1,600 people at Pierre Fabre Laboratories, compared to just over 400 in mid-2006. The company’s objective is to extend the GED application to other departments besides R&D and to complete the deployment in such a manner that all documents of an official nature will be located within a reference system in the future. Further plans involve the expansion of the Ophrys reference system, the construction of the DSI reference system, and the management of regulatory publications.

“The project is being extended in depth as well as breadth, and each new phase is being managed as a project in itself,” adds Adenis. “Moreover, with the recent deployment of EMC Documentum ECI Services, EMC’s multi-source interrogation solution, above Documentum and eRoom, we are in the process of moving away from content management towards genuine knowledge management. Structuring the information into reference systems and instituting a definite discipline proved to be indispensable prerequisites. This unified research tool, along with an increase in the number of users, will prove to be accelerators.”