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In search of experts: Pharmaceuticals enters next phase of KM

- **Kim Ann Zimmerman** of KMWorld Magazine

By Kim Ann Zimmermann

The actual product of the pharmaceutical industry—the drugs that help us fight disease—can be copied, as is witnessed by the explosion of generic drugs. If knockoff drugs can be produced fairly quickly after a patent has run out and the Food and Drug Administration (FDA) has given approval, how do drug companies differentiate themselves?

The management of knowledge—particularly all of the documentation that goes into producing a drug, and the marketing collateral and other materials that surround the process—is becoming the key differentiator to being first to market and maintaining relationships with the healthcare providers who make the ultimate decision about which drugs their patients will receive.

“Pharmaceutical has always been a classic KM-heavy industry, and we’ve always seen pharmaceutical firms deploying a lot of knowledge databases and workflow systems,” says Elby Nash, executive VP of Taratec Development, a technology consulting firm that has worked with a number of pharmaceutical companies, including Johnson & Johnson, Pfizer and Merck.

“The physical products of the pharmaceutical industry—while taking many years and an enormous amount of research to develop—can be copied pretty easily and marketed once a drug comes off patent," says Nash. "In this next wave of pharmaceutical KM applications, we’re seeing more interest in leveraging the tacit knowledge inside of people’s heads to gain a competitive advantage. Our experience is that KM has been implemented pretty inconsistently. What we’ve seen in the first wave of applications is that the systems have been, to some degree, technology-driven rather than being driven by the need to solve real business problems.”

One of the ways that pharmaceutical companies are working to leverage the knowledge of scientists and others who are involved in the development and research of drugs is by developing expert locator systems. Those systems, Nash says, help identify knowledge leaders within the company as well as outside experts who could be helpful during the product development lifecycle.

“We’ve seen some early adoption of these types of knowledge management tools, and they have been fairly successful,” he says.

Another KM tool that is gaining interest is the establishment of Web-based portals to manage all the documents and other pieces of knowledge associated with the product lifecycle development process.

“There is a lot of duplicate research going on at many drug companies, and this is a way of making everyone aware of what is going on throughout the company,” Nash says.

Tracking regulatory information

Open Text, which markets Livelink collaboration and knowledge management portal software, recently announced a customized solution for pharmaceutical companies, providing end-to-end lifecycle support for the large volumes of reports and other documents created during the discovery, development, testing and approval processes for new products. Called Livelink for Regulated Documents, the solution tracks the management of information to ensure compliance with rules from regulators, including the FDA.

"The key to success is to rapidly deploy new solutions that build efficiencies into the drug development process, while ensuring compliance with increasingly stringent regulations," says Martin Sumner-Smith, VP of pharmaceutical solutions at Open Text.

"Having key information immediately accessible via Livelink improves our efficiency and productivity, enabling us to fulfill the commitment we've made to patients that much sooner," says Fran Ross, contract associate with Genzyme, a biotech and pharmaceutical firm that uses Livelink. "Livelink is becoming a fundamental part of the way we work."

The authoring feature enables pharmaceutical companies to create document and workflow templates. In addition, multiple users can simultaneously review and edit documents, and the document release procedures can be created to comply with procedures established within the company as well as by regulatory agencies.

There is also increased interest in creating searchable databases of information collected during clinical trials. As the FDA and other organizations such as the International Conference on Harmonisation—which brings together the regulatory authorities of Europe, Japan and the United States, as well as experts from the pharmaceutical industry, to discuss scientific and technical aspects of product registration—move toward electronic submissions, KM will become even more crucial to the process, industry observers agree.

Livelink for Clinicals helps manage information and reports during the clinical trials phase of the drug approval process. For example, Severe Adverse Event (SAE) forms, which detail adverse reactions to new drugs among patients in a trial, can be scanned and routed through the system following established workflow guidelines.

On the move

The FDA has also recently implemented a KM system in its Center for Drug Evaluation and Research (CDER), which oversees the research, development, manufacture and marketing of all prescription, over-the-counter and generic drugs sold in the United States. More than 1,800 FDA scientists and researchers have begun using Convera's RetrievalWare to search a database of more than 3 million documents related to the approval, labeling and post-marketing surveillance of new drugs.

While KM is key to the drug approval and development process, managing knowledge in the sales cycle is also crucial to the success of the launch of a new drug. For example, AvantGo offers a mobile sales automation tool for the industry called Mobile Pharma. The system can access account information and physician data, as well as provide real-time access to medical and clinical research data.

KM tools also help when it comes to selling pharmacy benefits management coverage to HMOs, insurance companies and individual firms. Caremark, a provider of pharmacy benefit management services, is using a KM product from Pragmatech to manage proposals for new business.

"The first benefit was that we were able to establish an effective process," says Mark Ciamarra, director of proposal development at Caremark. "Prior to using Pragmatech, our proposal content database housed more than 30 separate folders. Each of those folders contained lengthy Word documents, some

exceeding 100 pages.

"In responding to RFPs, our analysts typically would perform word searches to try to find the material that would serve as the best foundation for formulating an answer, but this could necessitate searching many documents. Often, with the inevitable time constraints, they had to rely on their savvy and ingenuity and estimate which folders held the most appropriate material. Information was pulled and then cut and pasted into the draft document. We're really sitting on a pile of gold, but we have to be able to mine the information."

The system has also helped to manage the process for updating content. Ciamarra says, "The content is dynamic. We're always adding new statistics and new programs. We didn't have a way to proactively update the data." Now, when a new piece of content is created, a set timeframe—monthly or quarterly, for example—can be established to update the information. Caremark is also looking at a Web-based content retrieval system.

Kim Ann Zimmermann is a free-lance writer, 732-636-3612, e-mail kimzim2764@yahoo.com.

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