

KM shepherds drug development

- [Kim Ann Zimmerman](#) of KMWorld Magazine

It can take years and tens of thousands of documents to get a drug to market. KM makes the important job of pharmaceutical approval a little easier.

By Kim Ann Zimmermann

More and more, pharmaceutical companies are finding additional uses for drugs developed for a specific purpose. A product that was designed to treat high blood pressure, for instance, could stimulate hair growth. But when that drug is marketed to aid a condition or disease other than the one that it was originally developed to treat, drug companies must adhere to a second rigorous approval process. They would like to speed that process, and knowledge management systems could be the key, shaving weeks or even months off winning approval.

While pharmaceutical companies already rely heavily on KM systems, their importance will increase when the federal [Food and Drug Administration \(FDA\)](#) requires electronic submission of documents beginning in 2002. That move requires some standardization in the way that electronic documents are handled because drug companies use a variety of systems to help gather and organize the appropriate documents.

"Basically, when we submit a drug for approval, we're submitting all documents associated with the development and testing of that drug for the past five or 10 years," says Natalie L. McClure, VP of product development for [IntraBiotics Pharmaceuticals](#). "We're talking about submitting hundreds of thousands of pages of data. Some of that data is in the form of reports. Some of the data is clinical summaries of every patient treated with the drug."

IntraBiotics has installed a KM system from [CDC Solutions](#), which will be used initially to submit documents related to iseganan HCl, a drug for cancer patients. IntraBiotics acquired the software in March 2001 and has since run several test submissions in preparation for the planned new drug application (NDA) submission of iseganan HCl. McClure anticipates the submission to equal or exceed 300 volumes, or roughly 75,000 pages of paper documentation.

"Our customers are patients who suffer from oral mucositis and are undergoing chemotherapy and radiation therapy for treatment of head and neck cancers," explains McClure. "Presently, there are no approved drugs to either prevent or treat oral mucositis, which the patients often report as the most debilitating side effect from their cancer treatment. Isegegan HCl oral solution is being developed in response to this need."

McClure continues, "For a drug that does \$120 million a year in sales—which is conservative—even a month delay in filing or reviewing the data can mean \$10 million in lost revenue and a lot of patients suffering without a drug that could help ease their pain."

The CDC system, called EZsubs, enables the electronic assembly, pagination, book marking and cross-referencing with a primary table of contents for the submission, which McClure says will result in significant time and cost savings. "It's a little too soon to determine a return on investment, and we haven't tried to calculate labor savings yet, but the return will be enormous," she says.

One of the most useful features of the KM system is the hyperlinking capabilities, according to McClure. "You can look at summary documents describing data on 500 patients. Then you can drill down to get more detailed information. It operates in a similar way to Web pages," she says.

The system will allow the drug company to compile submissions with limited resources. "We don't have the luxury of bottomless funds or massive human resources to allocate for last-minute book marking and compilation of a major project like this," says McClure. "With CDC Solutions, we benefit by being able to streamline timely and low-financial impact processes where we previously would not have been able."

While KM will have a significant impact on the management of documents within an organization, it will also play a key role once the documents are submitted to the FDA for approval, according to Jim Cook, chief technology officer for CDC Solutions. "The goal is to increase the efficiency of the review," he says, "and knowledge management systems will play an important role."

As the FDA moves toward electronic submissions, the Internet could be used to submit new drug applications in the future. "The trend is to move toward XML technology," Cook says, which is the standard format for Internet documents. "It is not in place yet, but that's what everyone is talking about. It is all about improving the business process and pushing the process back up the submission chain. This empowers non-expert users to get at the information they need."

KM systems can also streamline drug research, according to Julian Henkin, VP of worldwide customer services for [LexiQuest](#). Henkin says drug manufacturer [Bristol Myers Squibb](#) is in the process of installing LexiQuest's search system to enable BMS' 5,500 knowledge workers to query documents on its pharmaceutical research intranet. The system is expected to be fully operational in early 2002.

"They've got all kinds of documents living on their intranet and researchers need to get to these documents quickly and easily," Henkin says. "The idea is to gather all of the necessary information as quickly as possible. You don't want a drug that hasn't been tested properly to get to market. But you have to streamline the document research and management in order to get these life-saving drugs to market as soon as they are ready."

LexiQuest allows a user to enter a query in natural language, which is then translated into technical language drawn from a specialized dictionary developed for the pharmaceutical industry. "The idea of our search engine is to help researchers find information better and faster through a natural language query implementation," Henkin says.

LexiQuest's technology determines the precise meaning of a word by its relationship to other words. In addition, LexiQuest's search engine incorporates a feature called synonymy. "This helps in the pharmaceutical industry because many drugs are referred to by several different names--generic names and other names. This search engine can pull up all the information on a drug--no matter what name it is referred to by in the document," Henkin explains.

Bristol Myers Squibb is also using the system to track news and other sources of information to keep tabs on the market and competitors. "Being able to automate this process and have information readily available to know what competitors are doing is key to success in any business, and it is especially important in the pharmaceutical industry where market conditions change rapidly," Henkin says.

While much of the emphasis of KM systems in the pharmaceutical industry is on research, transformation is also underway in the management of prescriptions. Prescription Solutions ([rxsolutions.com](#)) is using a system from Captiva Software ([captivacorp.com](#)) to automate order processing. The software captures data and images from paper and electronic forms and documents.

Prescription Solutions provides pharmacy benefit management services for commercial, Medicare and governmental health plans as well as employers and unions. With the new system, the firm estimates operational savings of \$500,000 per year, with a 14-month return on investment. It also has been able to more than double the number of prescriptions processed during an eight-hour shift. The company now fills 15,000 to 17,000 orders per shift, up from 6,000, and has achieved a 27% reduction in data entry staff, from 84 to 61.

"Our new electronic order imaging process allows us to stay well ahead of growing business demands," says Andrew Beyers, director of pharmacy operations for Prescription Solutions. "We can now focus on future business opportunities and have the assurance that our paperless workflow solution will scale as our business grows."

Rx for reaching potential

CIGNA Tel-Drug has embarked on a customer relationship management initiative to optimize the potential of its customer and prospect databases. A division of CIGNA Healthcare ([cigna.com](#)), the prescription mail order company wants its marketing department to understand customer behavior better so it can improve efficiency and attract more consumers and pharmacists to its program.

The initial mission of the project is to bring more pharmacy members into the mail order business to help members

reduce the costs of prescription drugs. Other goals include increasing satisfaction among pharmacists and consumers, providing supplemental education to customers to alert them to the mail order program, identifying eligible customers more readily, and tracking customers and their behaviors over time.

The project, which entails consolidation and centralization of 10 legacy systems, is fueled by CRM software and services from [Harte-Hanks](#). That company will provide strategic support in managing the CIGNA Tel-Drug database and will implement its Allink Xpert software as the CRM solution.

Says Aaron Crosson, CIO of CIGNA Tel-Drug, "The pharmaceutical industry is a highly competitive marketplace so to compete successfully, we made a business decision to market to our existing and potential customers more effectively.

"We also made the decision that to do so expediently would require the expertise of Harte-Hanks to help us eliminate the anomalies in our customer data, create truly unique customer identifiers and assist in our efforts moving forward . . . We truly believe CRM is an integral part to driving increased revenues and sales."

CIGNA Tel-Drug wants to realize the value of its customer and prospect databases so it can develop a network of customer-focused strategies, channel programs and campaigns, using a combination of direct mail and call center services. Allink Xpert is delivered as a hosted CRM solution, coupled with analytic support. It is in the roll-out phase at CIGNA Tel-Drug, with initial results from the implementation expected in the new few months.

Kathy Calta, group president of CRM data services for Harte-Hanks, says her company will build a central database from information pulled from the legacy systems, and conduct detailed analysis of the customer base through modeling, data mining and segmentation response analysis.

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