



The Role of Knowledge Management in New Drug Development

By Paige M. Leavitt

The growth potential for pharmaceutical companies in the present environment is tempered only by the economic and product development challenges they face.

With an increasing elderly population that consumes three times as many drugs as younger consumers, expansion into developing regions, and overall population/lifespan increases, the pharmaceutical industry has reached \$400 billion in worldwide annual sales of prescription and over-the-counter drugs. Equally encouraging for drug companies is a tremendously evolving product pipeline. Bioengineering, improved technology and laboratory research techniques, genomics, increasing R&D investments, and comprehensive content management systems are shaping sophisticated research data systems.

But with these opportunities comes immense pressure to deliver blockbuster drugs, reduce prices to compete with generic alternatives, and at least sustain shareholder value. In addition, there are heightened regulatory concerns, significant branding issues, impending patent expirations and short-lived profits, escalating R&D and operations costs, and the increased complexity in research data that comes with information overload.

Opportunities in the pharmaceutical industry have never been brighter, but only if companies can harness their knowledge to make better decisions faster.

The primary concern underlying both opportunities and challenges lies in drug development. "This is such a risky business," said Melinda J. Bickerstaff, vice president for knowledge management for the Bristol-Myers Squibb Company. "In what other industry do you develop a product in which you have to not only consider the quality of the product, but also the life/death health risk to consumers in using your product and constantly comply with ever-changing efficacy and safety issues from various regulatory agencies? And the cost is outrageous. We figure it costs between \$800 million to \$1 billion to develop a new drug and get it into the hands of consumers over a time span of 10 to 12 years."

As a result, the industry is increasingly relying on alliances and strategic partnerships with universities, biotech companies, and other drug manufacturers as a way of enhancing its pipeline of potential future products. Through mergers and acquisitions, major consolidation is taking place. Angela Boeckman, from Hoover's, reported that "building a bigger, stronger drug pipeline can stave off losses when best sellers go off patent, and the push for new blockbusters is also driving industry consolidation. Pooling R&D potential has been part of the logic behind such megamergers as those between Pfizer and Warner-Lambert, Glaxo Wellcome and SmithKline Beecham, and the companies that today are known as Aventis, Novartis, and AstraZeneca."

Carla O'Dell, president of the American Productivity & Quality Center (APQC), has noted that "the genomic revolution has unleashed a torrent of information that threatens to drown pharmaceutical firms unless they are able to know what they know, make better decisions about which molecules are the most promising, do it earlier in their discovery process, and do it faster than the competition. To add to the complexity, they must do it in concert with alliance partners. Fortunately, this is historically a research-focused and knowledge-intensive industry. Many of APQC's pharmaceutical members are launching or realigning their KM initiatives to address these issues.

A more deliberate and systematic KM approach is necessary for pharmaceutical companies in transition,

but by no means is it a simple solution to perfect the new product development process. "It's kind of like painting the train while the train is going at a very high speed," said Bickerstaff.

The Bristol-Myers Squibb Company, a member of APQC, has recently faced many of these industry-prevalent challenges, including a major acquisition and NPD improvement efforts in light of shareholder demands. Bickerstaff recently shared with APQC how knowledge management is enabling strategic partnerships, R&D's alignment with corporate strategic initiatives, an improved decision-making process, and the successful leveraging of intellectual capital.

The Bristol-Meyers Squibb Company

New York-based Bristol-Myers Squibb is the fifth-largest U.S. pharmaceutical company, with \$19 billion in sales in 2001. With 46,000 employees, the company focuses its efforts on oncology, cardiovascular and metabolic disease, infectious disease, neuroscience, and immunology and inflammation. Products include Boost, Excedrin, the diabetes drug Glucophage, and the cholesterol-reduction drug Pravachol.

"During the last five years, we've been very focused on improving our processes for drug development," said Bickerstaff. "The typical lifecycle time of development is about 10 or 12 years. There had been some statements a few years ago that we really wanted to try to speed that process up, certainly without causing any risk to patients in our clinical trials or consumers. But they thought that there must be a way to streamline the process and, hopefully, to get it reduced to seven or eight years. We realize there are simply a lot of parts we can't completely control, such as the outcome of clinical trials or the time to market through the regulatory processes."

Consequently, the company has been focusing its efforts on improving its overall operations. This includes changes in the way people work, changes in the processes they use, and changes in the technologies needed to support it all. Many issues were considered to address the time-to-market in drug development. For example, with massive chemical generation and screening technologies in place, companies can craft 10,000 new molecules a week. Bickerstaff described this as "an organization on data/information overload." She estimates that most scientists are spending 20 percent to 25 percent of their time looking for data and knowledge to get their work done.

Knowledge Integration Resources

The Bristol-Myers Squibb Pharmaceutical Research Institute (PRI) was established in 1938 to provide scientific information resources to serve the company's R&D function. In 2001 the Institute had a budget of more than \$2 billion and 50 compounds in active development. "KM efforts have been going on within R&D for a long time," Bickerstaff said. "Just no one labeled it that."

In early 2000 the company began to think about implementing a more formal approach to KM for R&D, as well as the enterprise. Bickerstaff joined in March 2001 to lead this effort. "When I came to Bristol about 18 months ago, the function known as the Scientific Information Resources (SIR) or the Research Library was serving the entire organization and not just PRI, but no one really knew that," said Bickerstaff, who reports to the chief information officer and to the company's IT organization, Information and Knowledge Management (IKM). "When I came, I was delighted to have SIR initially report to me, because my view was this is a group of professionals who truly are information specialists and whose primary business is managing knowledge for their clients. I thought that they could help lead the way to establishing more intentional approaches to KM throughout the enterprise."

Prior to her arrival, SIR, under the leadership of its group director, Carol Bekar, began to look at how work was being done, which processes were being used, and which technologies would be needed to help with decision making. Carol and her team visited KM leaders, such as Hewlett-Packard and Microsoft. This work led to the development of a strategy that transformed the library function.

The first step in this transformation was to change the name from Scientific Information Resources (SIR) to Knowledge Integration Resources (KIR), with the tagline, "Managing Knowledge for Competitive Advantage." This marked a fundamental transformation in the services it offered to the company. The group's role as information providers to R&D expanded to providing products and services to better

manage knowledge for the entire company. At the same time, Bickerstaff and the KIR team implemented a comprehensive, strategic approach to clients and services. "We've made a really conscious effort to describe services, rather than one-off searches and things like that, in order to transform the library function into a knowledge management function," said Bickerstaff.

KIR professionals developed training programs and began to aggressively market its new services. KIR also created its own marketing function to package the new products and services that it was developing for the enterprise. Surveys and interviews indicated many employees did not know the group existed, and many had not received training to use the extensive resources that were available.

Transforming the Staff

"When you bring a person in and give them the title of vice president for knowledge management, people ask, 'What kind of position is that?' I never heard of that before. Does that mean you 'know everything'? And what everyone has expected me to do is build a large function, which I haven't done," said Bickerstaff. "We are a company that is experiencing enormous change and transition. Since I've been with the Company, we've right-sized twice. And I've had no professional knowledge management staff officially reporting to me, other than the KIR professional group that I came in with 18 months ago."

As part of this transformation effort, a new role was created called the Knowledge Integrator. The information professional in this role serves as the single point of contact for the information and knowledge needs of departments and project teams in order to leverage the use of data and research and increase the speed and accuracy of decision making by scientists and business managers. In addition to assessing and fulfilling a team's information needs, the Knowledge Integrator filters and analyzes scientific, clinical, and competitive intelligence as it is published and then alerts team members to the latest advancements in medicine and biotechnology. Bickerstaff believes this alert service can be a huge competitive advantage.

We estimated that our scientists spend at least 20 percent to 25 percent of their time looking for stuff," said Bickerstaff. "We figured that if we could plant a person in their function -- biology or chemistry, for instance -- who was an information specialist and knowledgeable in the scientific area, then that person could be really valuable in thinking ahead, tracking the work they're doing, linking them to critical internal and external information, creating "alerts" and newsletters, and simply getting the knowledge they needed to get their work done. In doing this, we had hoped to reduce their own search time."

"In fact, the current team of 12 Knowledge Integrators has done just that by at least 5 percent to 10 percent," according to Bickerstaff. Furthermore, the Knowledge Integrators have become critical members of their teams and attend key operating committee meetings to provide input on the competitor patent environment and current scientific and business information.

Bickerstaff believes that the KIR transformed to a service and consulting model so quickly because the groundwork had been laid several years before. Then came the unexpected assignment.

Surprise!

In June 2001 Bristol-Myers Squibb announced it was acquiring the DuPont Pharmaceutical Company to expand its product pipeline -- a \$7.8 billion purchase. Once this purchase was announced, communication between the two companies was then largely restricted while under review by the FCC until October 1. The challenge placed before the organization was to complete this integration by year end, which was 10 to 12 weeks.

Bickerstaff said one of the greatest risks for this purchase was the potential loss of knowledge. While the acquisition was under review, "all of our competitors were actively recruiting the talent that we just bought, and we couldn't even speak to them." Because of the potential for knowledge loss, key executives were looking for a plan for both knowledge capture and knowledge retention. Suddenly, the role of KM within BMS was vaulted to both an enterprise and strategic level, because this became the most important initiative in the company at the time.

To develop both the plan and the implementation tactics for knowledge capture and retention, Bickerstaff brought in a key knowledge management consultant from Deloitte & Touche, borrowed several associates within the IKM organization, and tapped into the KIR organization for hands and information management skills.

The work for this acquisition was framed in teams called work streams. The work streams, which were KIR's clients, included critical therapeutic areas, support areas such as IT and human resources, and value areas such as facilities and finance. Services were developed that included: the creation of a clearinghouse of all publicly known knowledge about the acquired company, the training and education of scientists to capture their own soft and hard knowledge within a compressed period of time, the development of a plan to bring in nearly 18 million items of hard documents, and writing a knowledge capture playbook to codify this work.

Because Bickerstaff did not have a large KM staff, the only way to get this amount of work done in a short period of time was to ask for and train volunteers throughout the company. These KM volunteers were trained as facilitators, note takers, synthesizers, and writers. Nearly 150 volunteers were trained, and more than 700 others were either affected by or involved in these processes. This initiative created a prominent position for knowledge management and knowledge capture within the company.

Bickerstaff said, "My view was that if we captured 50 percent of the tacit knowledge that was available to us, that would be a smash. Because we were novices at this, and it wasn't like we brought in a herd of 20 consultants to go do this."

As a result of this positive experience with KM, senior management began to consider other issues or business problems that KM might help to address.

Creating Lessons Learned

"At the end of the DuPont acquisition in January 2002, we decided with the full sponsorship of the head of R&D to create and implement a lessons learned process for the R&D organization, which had not formerly been done here," said Bickerstaff. "The goal is to turn tacit knowledge and experience into actionable learnings that can be codified, shared, and understood by a wider audience. To do this, we convened the members and leaders of the work streams."

KIR held two-hour sessions of 25 people worldwide to capture lessons learned, with KM volunteer contractors, facilitators, note takers, and writers to codify knowledge. The final documents, which take a variety of forms from a Gartner-like report to a magazine article, were validated by the participants and will become a part of a mergers-and-acquisitions knowledge domain within a lessons learned repository that will be available for all employees in January 2003. This repository also will include a Knowledge Capture Playbook that is written as a series of articles.

"The idea was to have our professionals have an experience where they could do face-to-face exchange," said Bickerstaff. "The sessions were structured so that we would ask the stream leaders what they wanted to know about what happened and then design appropriate questions. We called that contracting."

"While this lessons learned process was going on, the executive committee of the company wanted to get a better understanding of why we were not getting our drugs approved as quickly as we planned through the regulatory agencies," Bickerstaff said. "We didn't have an approval rate that was any better or any worse than our competitors, but we wanted to find out why some of our drugs were approved and others were not." From February to August of 2002, the KM staff and its volunteer team reviewed a number of drug filings based on the structure of the lessons learned process. This group convened the teams involved in producing recently filed and developed drugs and performed a root-cause analysis to determine why some succeeded and others did not. The end products of this process were a series of case studies written like feature articles.

The findings of this work were translated into specific, actionable recommendations to improve the

company's drug approval processes. These were presented to every major decision-making group within the company including the executive committee and chairman. Once again, work streams were created for implementation, and KM leads were assigned to each. Their role is to assist in the implementation of the recommendations, as well as to implement solutions that will help teams share their work. This implementation will continue throughout 2003.

Enabling KM Through Technology

The KIR organization has created a seamless environment for accessing critical information, such as industry news, pipeline overviews, and electronic journals. Its digital library supports all of Bristol-Myers Squibb. The current collection includes more than 5,000 business and scientific journals, more than 1,500 sources of full-text reference information, and 20,000 downloadable e-books.

The KIR Web site was created to provide relevant and validated information, without delivering superfluous links. In addition to providing desktop access to content from externally published sources, KIR also manages the internal documents and has led efforts to provide companywide access to intellectual assets. This includes project-related information, an employee and subject matter expert directory, and the BMS Patent Portfolio, which is a digital library of more than 10,000 active BMS patents developed by KIR.

"The company had launched a portal two years ago," Bickerstaff said. "The chairman wanted a way to communicate with all 45,000 people in the company, so the technology people built a portal to do that." This became the enterprise platform for the emerging KM function within BMS.

This portal is also a space for communities of practice. "We've created a process at a strategic level in terms of creating communities in our enterprise portal, because we really want people to use the portal," said Bickerstaff. "We come from a company that has thousands of Web sites. So, we've created a process whereby people can fill out a request form and apply to develop a community either within or outside the [portal]. We have a board that reviews these requests and makes a decision. And we use a model to prioritize how strategically important are the communities. Out of this process surfaces the communities that are bubbling up in the organization in terms of readiness."

With nine communities currently in existence, there is a backlog of requests for community creation. Those communities have been defined in a number of ways. For instance, the purpose of one community is to bring marketing and manufacturing professionals together. And a community for resources is focused on providing access to databases. That information from the CoPs is then filtered back into the portal.

In fact, the development of an enterprise content management strategy is being led in part by the KIR organization and the portal development group. "Most companies are trying to have a consistent content/document application across the enterprise," said Bickerstaff. "Well, we don't have that. But we need to have that if we're going to manage knowledge through documents across the enterprise. ... Our goal is to come to agreement about the need for this strategy and to build the business case for implementation." Late 2002 and early next year will be devoted to promoting the value of this strategy to the business, with the assistance of the IT staff.

Staying on Track

BMS is just beginning to fill those portals with information from alliances and partnerships. It currently has about 50 major alliances with biotech companies and academic centers; corporate strategy relies on 30 percent of its blockbuster drugs coming from these alliances. The KM group plans to offer its portal as an enabling tool to future partners. "Most of these deals are financial deals, so you don't ask questions about process or culture," said Bickerstaff. "We're building all of that into the due diligence process. The other level is finding which databases, resources, or repositories are used by both groups so that we're able to bring that together quickly. ... I would really like knowledge management to be perceived as an integrator and as a facilitator for solving business problems."

In addition to alliance management, the KM group plans to focus on the due diligence process and

external development. "We're just beginning the process of pulling together learning and development, human resources, project development, informatics, and a couple of other areas to create a full-service consulting service to our full development teams," Bickerstaff said. "That's the next phase. And those development teams are critical for us getting drugs to the market."

And in the long term, the KM function may not only support new drug development but also transform the end product in an effort to have better-informed physicians, pharmacists, and consumers. "My vision for Bristol-Myers is that we will eventually move to the place where we will begin to think about not just selling products, but also selling the knowledge that we've accumulated while developing our products," said Bickerstaff.

Whereas many companies are inclined to temporarily shelve KM initiatives when faced with major competitive issues, Bristol-Myers Squibb is an example of how KM can be a primary tool to address those very issues. "From a business perspective, we've probably had our most difficult year in the history of the company," said Bickerstaff. "And we announced that our third-quarter earnings are down over 50 percent from a year ago. And we have numerous new senior executives joining the company so there's lots of transition going on. Yet, we've been brought in to assist with some of the major initiatives, the DuPont acquisition, and looking at our drug approval processes. This is high-risk. You have to deliver. But we've been able to deliver in a way that I think has been different for the organization."

Although the emerging presence of KM has not resulted in a large KM staff at Bristol-Myers Squibb, Bickerstaff continues to create KM professional positions in the midst of companywide restructuring and downsizing. She believes this attests to senior management's support of KM in new drug development and enterprise issues. Beyond that, much of KM's expanded role will involve employees from across the organization. "I think that managing knowledge differently needs to be a part of everyone's job," said Bickerstaff. "So if more people have an experience in which managing knowledge differently made a difference, then they will begin to think about how it might apply to them in their job. You've got to convert people one by one to being their own knowledge manager by giving them a positive experience and one that adds value to their work."

Melinda Bickerstaff will be presenting at APQC's Eighth Knowledge Management conference in Houston May 1-2, 2003. For more information, please visit <http://www.apqc.org/conf/km2003>.

Gaining an Edge Through KM

Knowledge management can play an important supportive role in the challenges facing the pharmaceutical industry. From content management to branding issues to managing costs to mergers to new product development to strategic alliances, APQC can help. Some of the world's largest pharmaceutical companies are members of APQC, including Abbott Laboratories, Bayer Corp., Boehringer Ingelheim Pharmaceuticals, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Pfizer, Pharmacia Corp., Roche, and Serono S.A.

APQC provides custom solutions, multiclient benchmarking, training and events, research, and membership services. The nonprofit organization has conducted many benchmarking studies relevant to pharmaceutical and biotech companies. Study findings are summarized in APQC publications, such as:

[Brand Building and Communication: Power Strategies for the 21st Century](#)

[The Changing Role of Strategic Planners](#)

[Community Relations: Unleashing the Power of Corporate Citizenship](#)

[Competitive and Business Intelligence: Leveraging Information for Action](#)

[Developing a Successful Competitive Intelligence Program](#)

[Health and Productivity Management II: Measuring and Reporting Work Force Productivity](#)

[Internet Marketing and Sales Strategies](#)

[Knowledge Management and the Learning Organisation: A European Perspective](#)

[Leveraging Customer Information: Driving Strategic Direction and Marketing Profitability](#)

[Marketing and Sales Strategic Alliances](#)

[New Product Development: Gaining and Using Market Insight](#)

[Strategic Collaboration for New Product and Service Development](#)

[Using Science and Technology Intelligence to Drive Business Results](#)

APQC's Knowledge Sharing Network contains more than 8,500 documents, many of which focus on pharmaceutical and biotech companies. A sample of relevant titles follows.

[Using Science & Technology Intelligence to Drive Business Outcomes - Boehringer Case Study](#)

[Developing Leaders At All Levels: Abbott Site Visit Summary](#)

[Improving Facilities Management Through IT - Pioneer Hi-Bred Case Study](#)

[Survival Strategies](#)

[Competitive & Business Intelligence: Leveraging Information for Action - Merck Case Study](#)

[Succession Management: Identifying and Cultivating Tomorrow](#)

[Side Effects](#)

[Benchmarking Benchmarking: Shared Learnings for Excellence - Amgen Case Study](#)

[International Purchasing - Merck Case Study](#)

[Merck Rx People First](#)

[Developing a Successful Competitive Intelligence Program - Glaxo Wellcome Case Study](#)

[Healthcare: Quality vs. Quantity](#)

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