



April Davis

Increasing workplace efficiency, saving time, reducing costs, and retaining, exchanging, and reusing knowledge are a few of the reasons companies introduce knowledge management systems. But if the four pillars of success — content, process, culture, and technology — are ignored, the tools may be shoved to the back of the laboratory closet.

Knowledge Management

The Four Pillars of Success

Knowledge management (KM) has a “shape shifter” history within the life sciences industry. KM responsibility has passed from department-level information technology (IT) sponsors to CIOs to enterprise-level eBusiness strategists. KM has transitioned from its initial focus on document management and technical issues to its current manifestation as a corporate initiative encompassing cultural retention and the protection of intellectual capital. These varying KM definitions, swings in KM adoption rates, and indefinite project timelines can cause the failure of KM initiatives. Other factors contributing to this KM graveyard syndrome include poor vision, lack of commitment, and misunderstanding about what is necessary to make KM successful.

By defining exactly what KM is and providing practical means for beginning a successful KM project in either large or small life science organizations (LSOs), perhaps fewer KM projects will fail. The results from successful KM in the life science community include increased workplace efficiencies, time savings, and cost reductions in business, research, and drug development.

KM Evolution

The current wave of KM strategies includes a three-part approach of process, culture, and technology. The emerging approach to KM rests on four pillars: content, process, culture, and technology. But before delving into this approach, it is important to understand what knowledge management is and what it can do for a life sciences company.

Knowledge — an end state of data. Data are raw elements that represent facts, events, or uncoded source records. Data elements become information when they are categorized based on logic or understanding. Information becomes knowledge when people use the information based on contexts they apply or when they derive information from which to make decisions.

To apply this process to life sciences, we can use genomic or cell-based sequencing and its evolution into proteomic knowledge as an example. Genomic sequences as raw data are represented by sets of cells that are the core working elements of human beings. A set of cells is categorized by chromosomal base pairs forming sequenced DNA or genomic sequences (the information surrounding the cellular structures). Genomic sequences contain information on how proteins or protein clusters are produced. It is the knowledge gained from understanding proteins and their potential effect on health and society that is the evolutionary stage of the human genome project (HGP). The process of deriving and applying knowledge according to dynamic protein changes and activities that target disease states illustrates the transformation of data (cells) evolving into knowledge (proteomics).

Beyond Data to Value

KM goes beyond managing raw data elements, information normally generated by systems or scientific instruments, or the data available in structured data stores. KM methodology includes identifying, capturing, evaluating, systematizing, and applying information and context to pour value back into an organization. Organizational value is measured in time, opportunity and opportunity costs, the quality of the products made, production costs, and — of particular importance — an organization’s competitive advantage.

KM’s value is measured by knowledge bases that are more than just structured or explicit data. KM includes the unstructured, real-time, human context applied to the data by the people that perform the daily activities (tacit information). Successful KM strategy creates an environment that enables knowledge exchange, retention, and reuse, a strategy encompassing the four pillars of KM success: content, process, culture, and technology (Figure 1).

April Davis is director of life sciences at Inforonics, Inc., 30 Porter Road, Littleton, MA 01460, 978.698.7300, fax 978.698.7500, april.davis@inforonics.com, www.inforonics.com.

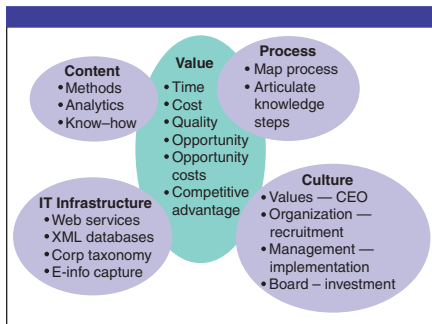


Figure 1. The four pillars of a successful management program

Four Pillars of Success

Building a successful KM program requires a firm corporate foundation supporting the four pillars of success.

Content — the starting point. Content, in the form of digital or paper-based assets, includes data, data stores, documents, faxes, correspondence, or any artifact that represents tangible work. In life science, content is a collective — a combination — of the drug research and the document assets that attend the drug development process.

KM originated in content management, which has traditionally been the starting point for many LSOs. Because of the regulatory environment in which life science processes take place, the necessity of retaining audit trails, and the proof required that all product development follows GMPs, LSOs needed to develop robust content management tools to manage and organize their research and development efforts. So, LSOs initiated an early form of KM to handle their content management, shelf-life issues, complex formulations, and structured taxonomic databases. Those document management systems pioneered the field of KM. For content to evolve into a tangible knowledge bases, however, the processes built from that content had to be created and integrated.

Process — the how and why. Process, as a KM pillar, answers the “how” and “why” of content management, and in doing that, turns content into knowledge. Business processes — the organizational business activities — help define an LSO’s intellectual property, its competitive advantage. For example, the way in which an LSO manages drug development costs and cycle times is measured by how well it defines its processes. An example of the process management needed in R&D is found in the LSO challenges of geographically dispersed research and

clinical labs, high turnover, and frequent mergers and acquisitions. Each challenge adds complexity to existing drug development methodologies.

Business processes can also be “virtual,” including the ways in which scientists, clinicians, and manufacturing personnel capture, create, and use research (content) to make decisions inside and outside the company. Virtual processes can be even more valuable in a KM strategy for an LSO than either content or formal organizational business activities. KM is about how people work together in a process to leverage their business content so that they can make decisions that improve business. Although content and document management have played big roles in KM’s early forms (in life sciences and other industry sectors), managers responsible for KM understand that value resides in process and content intertwined together.

Culture — top down, bottom up support. People (culture) add depth and dimension to a KM recipe. If business culture is left out of content and process initiatives, those initiatives become “silo projects” that either take too long to complete or are cyclically stuck in departmental quagmires while project reengineering or politics take precedence. An effective KM initiative must include remedies for the KM impact on the existing culture — to ensure the care and feeding of the business culture.

KM is successful when top executives sponsor and support knowledge sharing in real time, all the time. Knowledge sharing fosters an “us,” rather than a “me,” workplace environment. Top management must support the knowledge-sharing effort and promote its longevity. It is not enough for managers to support the process only at the outset of the KM initiative. Sponsorship presence, encouragement, and reinforcement are necessary to the recipe.

In life sciences, top management presence is crucial. In a successful knowledge sharing environment, scientists share their research and document their findings in a centrally managed location. Traditional repositories of scientific research — in inaccessible locations — will doom a KM project. Enforcing and encouraging collaborative scientific work can come only from the top. Incentive and reward programs encourage research sharing among scientist; corporate guidelines insist that “me-first” behavior won’t be tolerated.

Scientists and clinical lab staff can easily share data. But it can be quite difficult to set up a knowledge-sharing laboratory environment. Scientists work individually to create miracle drugs to cure diseases, progenitors in a “me” society. The habit of knowledge sharing requires time, commitment, recognition, and changed management strategies if it is to reap KM benefits.

Technology — adapting to change. The framework for a knowledge-sharing work place involves process-driven content capture, storage, and use, which is enabled through the fourth pillar of success: technology. Once the processes, content, and cultural dimensions have been defined, an LSO can create a technical infrastructure to support those efforts. To support content, process, and culture, IT personnel must create an agile and adaptable infrastructure that thrives on change. Changes can entail new computer systems, new practices from mergers or acquisitions, or new business processes inside and outside the company, between companies, or between the company and regulatory agencies.

Working in Unison

There is no shortage of data in life sciences, as testified to by the volume of information, new discoveries, and yet-to-be-identified leads that have come from the HGP. The life science industry is more concerned about where or how to mine those data assets and what technological framework to use to do that. Once content assets have been mined using a knowledge framework and presented on an intranet, then the process and the people provide the flexible approach, joining those newly mined assets together, making better decisions in less time.

The four pillars of a KM plan combined are of greater value than any individual component. A KM strategy that focuses on combining those pillars with a good corporate business plan ensures a successful KM initiative and offers a significant competitive advantage. Life science challenges drive the need for a four-pillared approach to KM.

The life science industry is heavily regulated, but that is not a new challenge. In an increasingly competitive environment, however, the effect of regulatory compliance on LSOs — electronic records and

Continued on page 58

Project Management continued from page 46

signatures, patient protection under the Health Insurance Portability and Accountability Act (HIPAA), and electronic submission requirements — increases the need for efficient research, collaboration, and content management practices in a content-rich industry. The volume of research data is not expected to decrease any time soon: Functional genomics and proteomics could produce up to 8,000 targets within the next four or five years.

Downstream in the production continuum, drug patents worth \$40 billion are expected to expire by 2005. That's almost 200 drugs. To fill that hole, classical pharmaceutical companies are looking at their drug portfolios, which are drying up. This fact has caused traditional R&D pharmaceutical companies to look upstream at biopharmaceuticals and biotech companies to mine, buy, or partner for compounds to increase their own portfolios. The outcome of these actions increases the process and cultural changes. To address the process

changes, discovery and product development activities need to be tightened and aligned. For cultural changes, homogeneous environments need to integrate the shift to heterogeneous and geographically dispersed work environments.

As if that wasn't enough change, Tufts University in its November 2001 annual drug study report estimates that drug development today costs \$802 million per drug (1). To provide context, Tufts stated that a drug's development costs were \$231 million in 1987. Drug development costs must be capped and made more efficient to reap sales revenues in today's competitive marketplace.

As LSOs face these emerging challenges, they could greatly benefit from a thoughtful KM strategy that combines the four-pillars. A collaborative knowledge-sharing team environment is necessary for innovation and ultimately for better products. When scientists know that they must work together, the risks of research or document

duplicity, reinvention, and errors are reduced, resulting in cost and time savings. When objectives are known, shared, and understood as common goals, the path to success becomes simpler and reachable. Also, as knowledge sharing organizations endure and form habits, cyclical metrics can be collected and evaluated for common goals, promoting clearer paths, getting better results, increasing the throughput of potential drug candidates, and therefore reducing cycle times. An appropriate technological infrastructure can deliver appropriate knowledge to the right people who can then make the right decisions.

Reference

- (1) J.A. DiMasi et al., Tufts Center for the Study of Drug Development, press release, 30 November 2001. **BP**