# Role of Knowledge Management System In Pharma Industry

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In this article, we explore how we anticipate **knowledge management** might continue to evolve and benefit, especially in the context of the **Pharmaceutical Industry**. The ongoing shift from a paper world to an electronic world has been both a blessing and a curse for the pharmaceutical industry. On one hand, the Internet has made available a vast trove of external

information and research data that, in the past, had been difficult to tap. A significant downside, though, is that there is a lot more data to be found, stored, and maintained.

Therefore, the <u>pharmaceutical companies and the biotech industry</u> are increasingly turning to knowledge management (KM) to help them succeed. <u>Knowledge Management</u> can improve productivity in the face of an increasingly complex R&D process (the main department of a pharma company), allow the sharing of data and information between different parts of an organization, and enable the sharing of expertise with partnering companies in cases of licensing deals and acquisitions and mergers.

Knowledge management is a process whereby companies identify, store, share, and reuse their own data, external information, and most important the business knowledge and experience of employees. Knowledge management is not just about technology, but also about implementing new business processes.

Knowledge management is the company's ability to benefit from the experience and expertise of its people. It's a way for companies to retain this information, document it and transfer it to somebody else.

— Jim Murphy

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# Supportive Role of Knowledge Management in Challenges Faced By Pharma Industry

The *pharmaceutical industry* has the potential to be among the hardest hit by the boomer **brain drain**. The risk of intellectual capital loss is greatest in enterprises whose success depends heavily on specialized knowledge and a capsule description of the pharmaceutical business.

Corporations have invested billions of dollars in establishing processes and implementing technologies that enable them to leverage corporate information while avoiding its loss. An obvious danger is that key professional and technical staff may retire or leave for greener pastures, taking with them the knowledge and business information stored in their brains. In a survey by recruitment firm Robert Half International, 55 percent of executives polled said their companies were concerned about losing key staff to retirement in the next five to 10 years. In addition, 78 percent reported that their companies were taking steps to mitigate the effect of the loss of these employees. Some companies forestall the problem by retaining would-be retirees as consultants or part-timers. However, a more permanent solution is to invest in technology that fosters and helps automate the knowledge management process.

The **pharma knowledge management software** is gaining maximum traction in recent times owing to its features and capabilities, such as identifying, capturing, evaluating, retrieving, and sharing information. Upon this, Market Research Future study reveals that the <u>global pharma knowledge management software market</u> is to **double its market valuation by 2023** by climbing USD 2 Billion at a CAGR of 17% between 2017 and 2023.

Most pharmaceutical firms are using a variety of technologies and processes to retain and transfer knowledge from their R&D and manufacturing professionals. Typically, a good knowledge management approach includes document management systems and collaborative online workspaces in effect, networked systems that foster the sharing of ideas, experience, and knowledge among colleagues. The backbone for sharing scientific data and other R&D information is the company's international knowledge management system.

A knowledge management system is responsible for the integration and delivery of external content and internal scientific data for decision-making. PHPKB is one such knowledge management system that supports the interaction and sharing of information by scientists and researchers throughout the company.

Although only a handful of new drugs make it to market each year, pharmaceutical companies must carefully track all of their research and **supporting documentation** to replicate success and to learn from past projects, even failures. It's not just a matter of gathering the data but **analyzing it to spot patterns and trends**. A clinical trial can involve thousands of patients nationwide. Knowledge management systems can automatically recognize unexpected results and route them to appropriate people for analysis. They can help save time and ensure that crucial information is not overlooked. A centralized knowledge management system acts as an easily accessible repository that enables us to supply our customers with timely and accurate information on our product.

Knowledge management isn't limited to the drug development process, this really **enables the pharmaceutical salesperson to have an interactive and meaningful conversation with the physician**. Plus, the sales staff can review and share comments from physicians. The need to share information doesn't stop once a drug is developed. Many pharmaceutical companies face the challenge of managing the information that is accessed by their sales representatives in the field. Those sales representatives need to interact with physicians and provide accurate information about the drugs.

# Sources of Knowledge for the Pharmaceutical Industry

Knowledge management is a systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes, and components.

Sources of knowledge include, but are not limited to:

Prior knowledge
Pharmaceutical development studies
Technology transfer activities
Process validation studies
Manufacturing experience
Innovation
Continual improvement
Change management activities

# Features of Pharma Knowledge Management System

A knowledge management system should have a powerful workflow engine, strong search capabilities, document sharing solutions, and document viewers. The knowledge management system should be responsive (desktop and mobile-friendly), with integration capabilities such as Active Directory integration, and should support multi-language knowledge accumulation.

### **Effective Knowledge Base**

The need to have a centralized repository of knowledge is critical. Pharmaceutical industries are flooded with documents to manage: everything from GMP documents to process/product/analytical development reports, meeting minutes, and project analysis documents.

- 1. The knowledge base must accommodate data and documents from multiple sources, none of which is wholly dedicated to a given sponsor.
- 2. Knowledge documents ownership change as corporate ownership of project changes.
- 3. Ease of file sharing and the leanest of companies means that libraries have limited curation, yet people want more data-mine ability.

### **Document Management**

The software should come equipped with document management features and be capable to store documents and records electronically and make them easier to find and manage throughout their life cycle. PHPKB knowledge management software can benefit any organization small or large to create, store, and manage electronic documents and records in an easy-to-use knowledge base with advanced functionality which makes searching and finding documents and records much easier than on a typically shared drive environment.

#### **Automatic Notifications**

Automatic notifications are the communication sent by localists directly to a user. An efficient notification system helps you send real-time updates and reminders to engage your audience with your company. PHPKB knowledge base software not only has an external notification system for end-users but also has an internal notification system for your knowledge base administrators. A pending task notification and review notifications are sent to team members when a task is in staged status.

# **Collaboration System**

Collaboration means working together with people from across the business to achieve a shared goal. The collaboration feature allows team members to share their views, ideas, opinions & comments in the form of notes with other users to refine the content of the knowledge document. The intent of this collaboration is to polish the documents and to bring them

up to the highest standards.

### **Document Versioning**

Document Versioning refers to the creation and management of multiple releases of a document, all of which have the same general function but are improved, upgraded, or changed. Versioning is the process of assigning unique version numbers to the unique states of a document. These numbers are generally assigned in increasing order and correspond to new changes in the document. This also helps to know what changes were made to a document over time and compare different versions of a document. Many companies are required to maintain a history of the documents that they house on knowledge.

#### **Full-Text Search**

PHPKB knowledge management software has an incredibly fast & accurate knowledge base search engine that provides full search capabilities to knowledge base users. It searches among categories, articles, attached documents, and custom fields. All searches in your knowledge base run on a full-text search system, which provides extremely fast and incredibly accurate search results. Each article in the search results is ranked based on its relevance i.e. most relevant documents are displayed at the top of search results and words from the search query are highlighted in the search results to ease in searching for relevant information.

### **Audit Log**

Event logging feature that tracks who, what, when, and where. This helps admins monitor performance and keep track of potential workflow disruptions. Tracking changes without an event log is easy in a small knowledge base because the changes can be conveyed to the team verbally or through emails. However, keeping track of changes in a large organization with many users is tedious. Therefore, changes made to a specific module in a knowledge management system should be easy to track, so every administrator is aware of the changes made by the account holders. The knowledge base event log in PHPKB knowledge management software helps oversee these changes made in the knowledge system and the event log focuses on four key areas:

What change was made? Who made this change? When it was made? Where the change was made?

# Critical Elements to Ensure Knowledge Management System Meets ICH Q10 Guidance

**ICH Q10** is a model for a pharmaceutical quality system that can be implemented throughout the different stages of a product life cycle. Much of the content of ICH Q10 applicable to manufacturing sites is currently specified by regional GMP requirements.

# **Information Acquisition**

It is critical that tacit knowledge (knowledge that is "in the head") is converted to explicit knowledge (knowledge that is documented and able to be disseminated). You may wish to know more about tacit and explicit knowledge.

Ensure that knowledge management is incorporated into processes by utilizing logical standardized procedures to define requirements for documenting information and minimum requirements for the type of data to obtain in specific processes. Assign responsibilities for knowledge management i.e. who is responsible for acquiring and documenting data?

When in doubt, document. The acquired information may have relevance in another stage of the product life cycle.

Store acquired information in a secure manner e.g. document management system, secure knowledge base system, etc.

#### Information Distribution

Acquired information needs to be communicated internally (and potentially externally). Document management systems such as PHPKB are capable of controlling and promoting access to specific information.

Management should advocate effective communication of information and empower employees to share information in an open and effective manner.

Retaining knowledge (tacit knowledge) should be discouraged by management.

Quality-related processes should be promoted by management and communicated to all levels and functions within an organization. Communication should be encouraged between all levels (upwards and downwards) of an organization.

#### Information Utilization

Since knowledge management and enhanced process understanding are critical to continuous improvement, pharmaceutical companies should make a concerted effort to collect all relevant technical and quality data, store data in a secure environment (physical or electronic), and communicate or provide access to all levels of an organization.

# **Knowledge Management in the Pharmaceutical Sector**

When considering KM, in particular as a key enabler in delivering the objectives of ICH Q10, three key questions that arise are:

- 1. What are the opportunities for KM to have a meaningful impact in the pharmaceutical sector?
- 2. How can KM help pharmaceutical companies deliver medicines and other therapies to patients more rapidly?
- 3. How could an effective KM program support operational efficiencies for the company, improve employee engagement, and help address the many other challenges that face the sector?

### **Knowledge Management Focus Areas**

In a publication entitled "Knowledge Management Foundations: Thinking about Thinking - how People and Organizations Represent, Create, and Use Knowledge", the author Wiig introduced eight important knowledge management concepts which are listed below.

- 1. Survey, develop, maintain, and secure the intellectual and knowledge resources of the enterprise.
- 2. Promote knowledge creation and innovation by everyone.
- 3. Determine the knowledge and expertise required to perform work tasks, organize it, make the requisite knowledge available, "package" it (in training courses, procedures manuals, or knowledge-based systems, for example), and distribute it to the relevant points of use.
- 4. Modify and restructure the enterprise to use knowledge most efficiently, take advantage of opportunities to exploit knowledge assets, minimize knowledge gaps and bottlenecks, and maximize the value-added knowledge content of products and services.
- 5. Create, govern, and monitor future and long-term knowledge-based activities and strategies and particularly new knowledge investments R&D, strategic alliances, acquisitions, important hiring programs, etc., based on the determined opportunities, priorities, and needs.
- 6. Safeguard proprietary and competitive knowledge and control the use of knowledge to ascertain that only the best knowledge is used, that valuable knowledge does not atrophy, and that it is not given away to competitors.
- Provide KM capabilities and a knowledge architecture so that the enterprise's facilities, procedures, guidelines, standards, examples, and practices facilitate and support active KM as part of the organization's practices and culture
- 8. Measure the performance of all knowledge assets and account for them at least internally as capitalized assets to be built, exploited, renewed, and otherwise managed to fulfill the organization's mission and objectives.

# Types of Knowledge Management in the Pharmaceutical Market

On-Premise Cloud-Based (SaaS)

# Applications of Knowledge Management in the Pharmaceutical Market

Medical Biotechnology Animal Biotechnology Agricultural Biotechnology Environmental Biotechnology Forensic Biotechnology

# Key Players in the Knowledge Management in the Pharmaceutical market

Oracle

SAP

Altair Engineering

Lucidea

Chadha Software Technologies (PHPKB)

Bloomfire

IBM

### Conclusion

The pharmaceutical industry faces a unique set of industry characteristics that make it an ideal candidate for knowledge investment. The industry's reliance on human and intellectual capital, high level of competition, large first-mover rewards due to patent protection, highly distributed organizations, and a high percentage of repeat work, provide the pharmaceutical industry with the potential for a high marginal benefit from knowledge management investment.

Pharmaceutical companies can leverage knowledge management and increase their product development speed. Any pharma company that utilizes knowledge management can start the profits rolling in sooner and outpace its competitors.

Leveraging knowledge can make a crucial difference. As employees in a company share and reuse knowledge, big savings in one location rapidly multiply to impressive numbers across continents. The bottom line is that knowledge is the most important asset in the Pharmaceutical industry. What we know, how well we use it, and how quickly we can learn new things, makes you competitive. It can give you an advantage that makes a difference.

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