

# BPM in the Pharmaceuticals Industry

## Overview

The Pharmaceutical industry has been constantly evolving due to globalization, consolidation and regulatory compliances. Manufacturing needs to incorporate more efficient, quality-centric processes. A pharmaceutical supply chain has to be scalable and agile enough to accommodate changing scenarios and partners across the globe. Research and development (R&D) is under pressure to cut costs and cycle time.

As managed care organizations limit drug formularies and promote generic drugs, pharmaceutical companies are developing strategies to compete with generic drugs. Staying competitive in this evolving environment has never been more challenging. Sales and marketing must address regulatory demands by re-evaluating how they manage the increasing number of channels and partners. Amidst this backdrop, efficient management of business processes is essential for sustenance and growth. The standard BPM solution enables the organization to manage the workflow and electronic forms processing dynamically with its powerful BPM.

A business process management (BPM) value chain approach to study these issues:

- Provides a way to identify enterprise-wide value-generating opportunities.
- Provides a business framework particular to the enterprise, which helps identify root causes.
- Facilitates business process discussions within an organization resulting in better decision making.
- Helps prioritization of major initiatives by linking them to the desired objectives for the business.
- Allows performance benchmarking against competition.

## The Problem

Pharmaceutical industries face tremendous competitive pressures and regulatory analysis which requires a unique approach to providing business solutions. The BPM improves the flow electronic forms efficiencies on extensive R&D processes, clinical trials tracking, QA lifecycle management, FDA approvals, marketing, and sales.

## The Solution

BPM offers a powerful solution for the pharmaceutical industry that enables you to be standard compliant and optimizes your ROI.

- Automate, simplify and manage clinical trials processes
- Shorten the time to market and minimize risks and errors
- Ensure regulatory compliance without significant cost increases
- Improve communications and facilitate a collaborative research environment
- Greater accuracy in records and processes
- Gets drugs to the market faster
- Project management
- Quality assurance

## The Challenge

The BPM solutions help Pharmaceutical organizations to increase the quality and consistency of their increasingly complex and highly regulated business processes. Due to the regulatory nature of the pharmaceutical industry, the specific functions of product design and development, material

procurement, production, distribution and logistics, and administration are distinctly different from any manufacturing organization. The challenge is to reduce the burgeoning costs of clinical trials, research and development, and sales and marketing by streamlining supply chain and production processes. The BPM can help in implementing efficient and integrated processes and systems which automate and streamline corporate administration, product development, operations, supply chain and customer interface.

- Project management
- Electronic batch records management
- Long-term data archiving
- Quality assurance
- Data acquisition & analysis
- Scientific data management
- Records management
  - New product introductions
  - Multi-vendor instrument control
  - Regulatory Compliance

Features of BPM Solution:

- Electronic form processing
- Business Activity Monitoring - BAM
- Form creation without coding
- Database connectivity without coding
- Creation of Workflow without any programming
- Web based eform processing
- Serial and parallel routing
- Form processing through Mobile devices

## Pharmaceutical Industry Overview

The global pharmaceuticals market generated total revenues of \$577.1 billion.

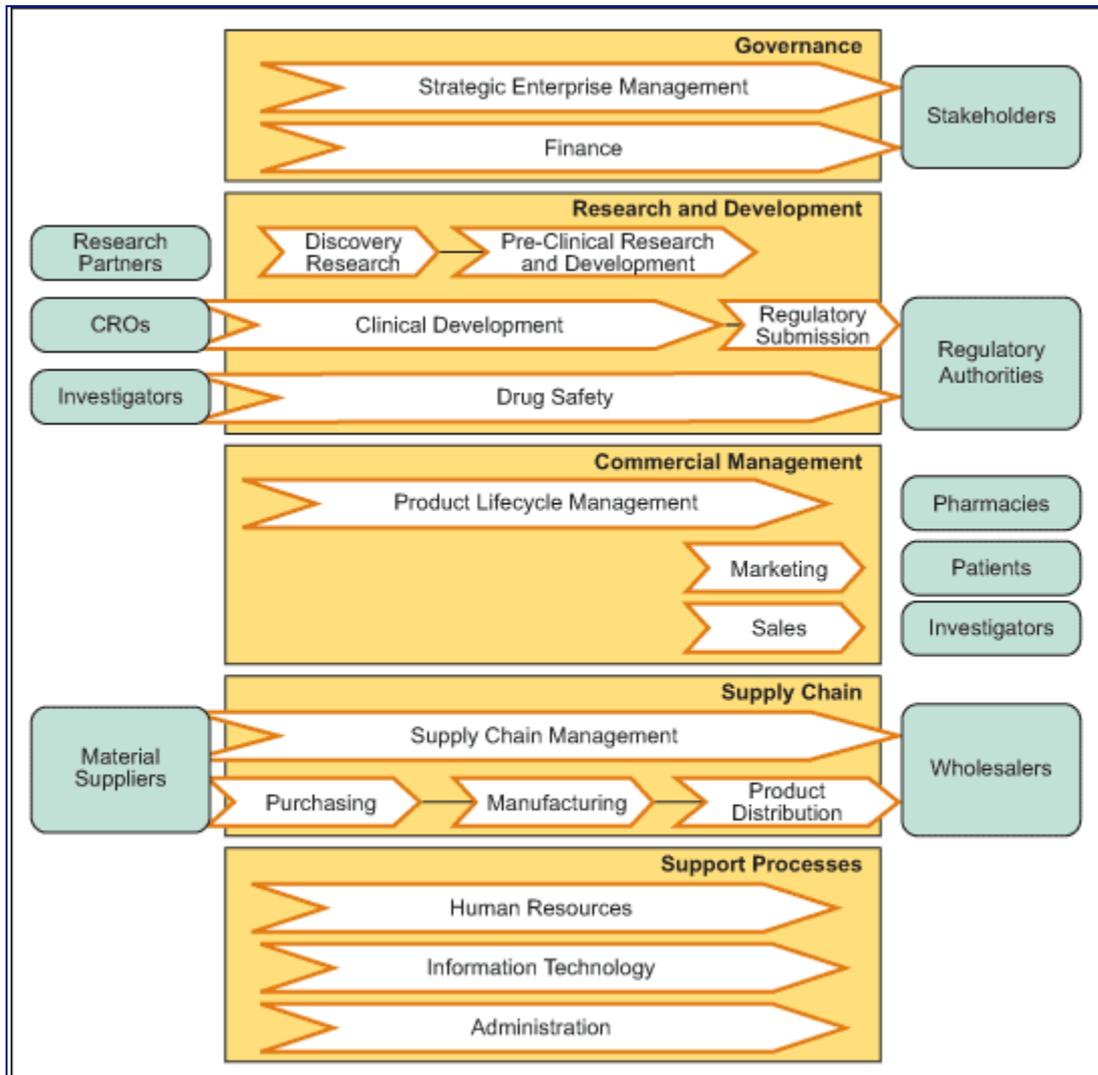


To analyze how BPM can help organizations in meeting these challenges, it is important to the industry is experiencing increased pressure to change at fundamental levels, caused in part by:

- Constant pressure to cut drug development cost and cycle time.

- Customers demanding more innovative pharmaceutical products at more competitive prices.
- Expiring patents on existing blockbuster drugs.
- Tighter industry regulations.
- Gaps among people, back-end systems, and critical processes and initiatives.

To analyze how BPM can help organizations in meeting these challenges, it is important to understand the pharmaceutical value chain.

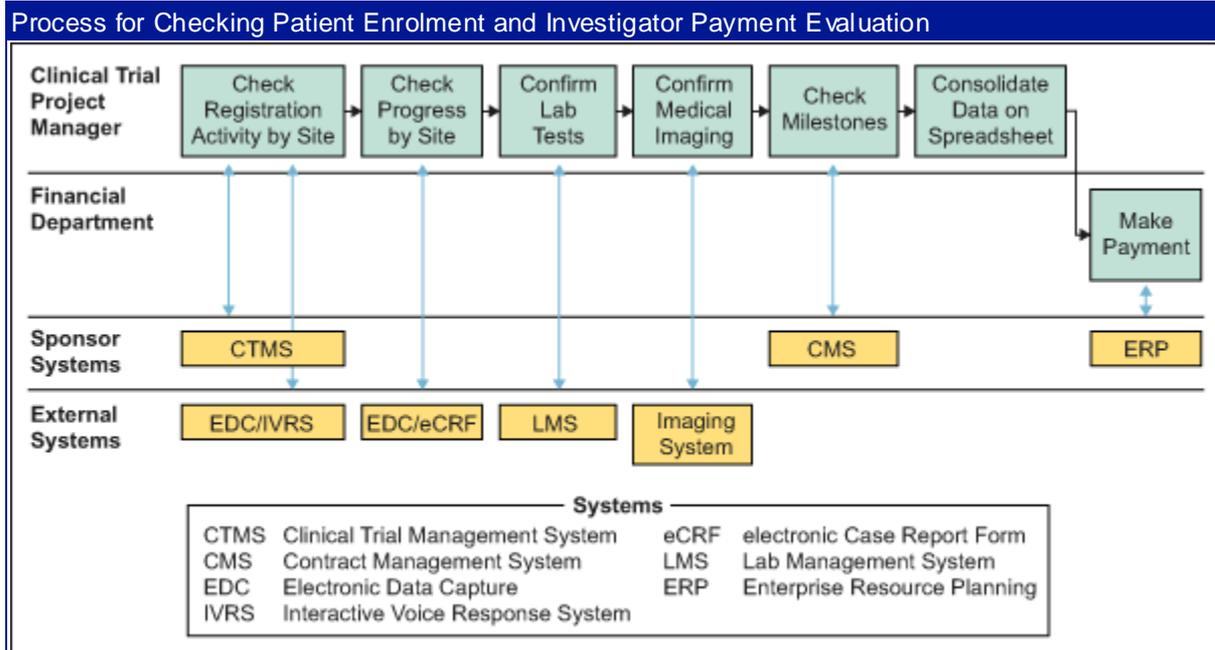


In this overall context, the key issues and possible solutions from an information perspective are shown below:

Pharmaceutical Value Chain Issues and Solutions		
Area of Value Chain Affected	Business Issue/Challenge	Potential Solutions
All	Sharing of knowledge and collaborating with partners	Information that is visible and transparent in real-time to be shared internally/externally
All	Ever-increasing volume of complex data, which has to be integrated and queried	Taking a process-centric view and integrating multiple sources of information to enable efficient combining and querying of large amounts of data
All	The priority of products in the development portfolio is unclear/keeps changing	Creating and managing a balanced commercial portfolio aligned to corporate objectives
All	Tracking and modeling of resources – balancing demand for product against capacity	Integrating supply chain planning, executing alliance partnerships/strategies
R&D, manufacturing, supply chain	High cost of R&D, distributions and logistics, and verifying consistency of product quality	R&D, compliance and distribution channel strategy development, Six Sigma
Sales and marketing	Managing contacts and relationships within a multi-channel sales environment	Customer relationship management

Not only managing clinical processes, but also making them more responsive, is increasingly difficult with the involvement of external partners including clinical research organizations. Clinical development must work hard to effectively manage investigator relationships and clinical trials across disparate applications.

Most organizations lack end-to-end visibility of clinical trial processes. Considerable manual intervention is required for management with a lot of room for improvement.



Consider an example: a pharmaceutical company is using a paper-based clinical trial process and they are approaching increase data throughput. Business process mapping and analysis can help find out the processes that can be automated like selection and registration, and can give better control over its paper-based processes. BPM implementation will help ease the incorporation and monitoring of business conditions. Business processes to route scanned documents for review and approval can be implemented in the same fashion and as the company's needs grow, other processes can be added.

If a clinical trial system already exists, BPM can provide a means to adopt a process view and inter-connect with other enterprise systems like an ERP system, a lab management system (LMS) or a contract management system (CMS). BPM helps build in efficiency in a number of ways by enabling:

- Real-time access to study progress: Information is accurate and up-to-date – exchanged at the point in time it is needed.
- Preservation of existing IT investments: BPM can communicate business tasks concerning specific data recognized among existing systems and applications helping to extend their longevity regardless of geography, number of sites or trials.
- Reuse: Services can be used by systems like an enterprise data system for clinical studies, and by all EDC systems used by partners.
- Enforcement of compliance: As processes are properly governed and updated, it can help enforce sponsor-level compliance and consistency across applications through system collaboration.
- Facilitation of business process change: BPM make it easier to change and scale the business processes required for clinical trials. Processes can be easily accessed and applied to other systems.
- Expansion beyond organizational borders: BPM offer a standards-based approach to systems integration. Processes may be exposed locally or globally with select partners such as IT providers, logistics services, randomization providers and other vendor services important to managing studies.

## Supply Chain

All pharmaceutical companies must improve the productivity of their manufacturing assets and capital efficiency over a sustained period of time. In other words, they must learn to make better use of their plants and people, and reduce their fixed costs.

Three elements are essential here:

- 1) a Lean manufacturing culture,
- 2) long-range modeling and
- 3) an integrated supply network.

Although Six Sigma, the methodology for measuring and reducing product variation, sets a target of six standard deviations between the mean and the nearest specification limit, most pharmaceutical companies still manufacture to standards of only two sigma. Adopting a Six Sigma culture helps a company increase its productivity and reduce cycle times by eliminating waste. It also saves money; moving from two to four sigma typically results in a 15 percent cut in costs.

Creating a model of the economic and physical forces influencing the supply chain, and simulating the end-to-end process (including market demand, capacity and costs), enables it to identify which levers it should pull and what effects it will have. Lastly, building a network of trusted suppliers and integrating them in the supply chain ensures the model is comprehensive and makes it easier to coordinate responses to a change in demand, supply or production. Synchronizing the manufacturing process involves sharing information on the design and movement of the products being manufactured, using track and trace technologies like radio-frequency identification (RFID) to provide real-time data on progress along the production line. It can deliver substantial productivity gains, as well as reducing the amount of capital that is tied up in stock.

## Sales and Marketing

Successful sales and marketing efforts rely on accurate and timely information – getting the right message to the right people at the right time. At the same time, the pressures on the healthcare market are strengthening the roles of other stakeholders – providers, payers and patients, for example – who must now be targeted through a combination of channels. Additionally, the message concerning innovative products is becoming increasingly complex with more information needed on product safety and cost.

Compliance with regulations across the globe is a must; regulations differ among countries and limit, among other things, how often sales and marketing can contact a prescriber, or how much they can spend on these interactions. Tracking and coordinating these interactions is further complicated by systems that are not currently integrated or are connected through point-to-point solutions with fixed interfaces. Often, they have no overarching architecture or governance to enforce regulations.

Information about physician interactions within a channel is often hosted by marketing agencies outside of the pharmaceutical company or housed in independent databases. Relying on independent data sources like these makes it difficult to synthesize and evaluate the volumes of information available to determine the optimal combinations of channels. Analysis and reports can help address these issues with information that can be updated in the application within the respective businesses. It is not evident that issues exist, and compliance actions are needed, until the reports are generated. But these reports are not available until the analytical environments are set up or refreshed. Once a compliance action is identified, a request is routed back to someone who can update the system controlling the requirement. As time passes, the company can move farther and farther out of compliance. As a result, many pharmaceutical companies are unable to provide access to clean, reliable information in a flexible, reusable manner.

Many of the challenges described in this scenario can be addressed with business rules technology of BPM, which uses a rules engine. This allows the execution and management of business rules, which

can then be used by multiple applications. BPM enables analyses that can improve decision making across many parts of the organization:

- Reuse data/repeatable processes: Services can use business rules that can be validated and reused – without revalidation – to adapt to and enforce changing regulations. These, in turn, enable analytics that can provide insights for decision making when users are approaching thresholds.
- Increased flexibility: A rules engine allows business rules to be isolated from the applications. It can provide granular access to specific functionality in a business application, such as setting a restriction on a spending level. The business rules can be as simple or as complex as needed that can be applied across many different situations.
- Reduced errors: Systems are updated by other systems. If a compliance report shows an activity that needs to be restricted, this can be done without having to re-key information or rely on manual approaches that can introduce human error.
- More efficient partnering: Sponsors that rely on partner-acquired data can have easier access to reports and data sources as they evaluate information to make decisions more efficiently. This visibility can also be used to gauge how well a partner meets the milestones and obligations outlined in contractual agreements.
- Support new business strategies: It permits a broader view of interactions with influencers enabling them to reduce repetitive contacts, build on previous discussions and coordinate interactions. Ultimately, this can help heighten efficiencies, foster credibility and potentially reduce spending. As organizational leaders develop a broader view of their internal landscape, they develop a better understanding of the combinations of channels that can help them plan their strategies domestically, as well as in new markets.

## Summary

In order to derive continuous value from processes, a pharmaceutical company needs to focus on the following activities:

- Design of business models and processes across value chain
- Effective acquisition of processes and technologies in a timely manner
- Implications for supporting information technology infrastructures
- Implementation of a systematic review of internal processes

Uncover the hidden value in these processes is not just a one-time exercise – it is necessary to update findings as the landscape changes. Organizations must regularly ask themselves:

- Are the core processes mapped formally and consistently across the company?
- Are the core processes up-to-date?
- Have the processes been mapped by department and function, or are they cross-functional (e.g., project management process, processes supported across functions by IT)?
- What is being done to identify and prioritize issues?
- Are there cross-functional issues or problems that need addressing? How will they be addressed?
- What is driving value in processes that can be further leveraged?
- Are there any opportunities to leverage findings across different parts of the value chain?
- To what extent are processes understood? Is how to fix problems and leverage opportunities clear?
- When has a company reached its optimal performance for a process?
- What is the anticipated impact of planned initiatives and projects on the drivers of value?