Guiding Principals of
Submission Process Management

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Jim Walker

PROCESS MANAGEMENT

is an emerging concept in the world of biopharmaceutical research and development. There are numerous macro business drivers that have necessitated the development of business process management principles within clinical research and development. According to the Tufts Center for the Study of Drug Development, the current cost of bringing a new molecular entity to market is estimated at $897 million. This cost has been estimated as high as $1.7 billion by the consulting firm Bain & Co. To compound matters, the threat of price controls, generic competition, and a reduced reliance on blockbuster drugs have all served to squeeze profit margins in recent years.

"One of the most prolific business drivers is the institution of electronic reviews at health authorities worldwide," says Jim Walker, president and CEO of Octagon Research Solutions. "The industry is moving toward an ever-increasing volume of electronic submissions, the complexity of which continues to grow. Managing this volume and complexity is a daunting task."

At the micro level, the emergence of electronic submissions has created more moving parts. The ICH, HL7, and CDISC initiatives are transforming traditional functionally isolated activities into cross-functional process-centric concerns.

According to Mr. Walker, to deliver on the promise of electronically transforming clinical research and development, it is important to have visibility into the process.

"Being able to track, monitor, measure, and optimize processes in real time is vital," he says. "Moreover, it has become critically important for development teams, who are dispersed around the globe, to have insight into each stage of a product's life cycle."

Organizations face many issues surrounding the submission process. With the emergence of electronic submissions, the submission process is no longer just a regulatory affairs or regulatory operations concern.

"The submission process has rightfully permeated throughout clinical research and development into the functions upstream from regulatory," Mr. Walker says. "With this permeation comes a fundamental change in the way the process is conducted. There are new deliverables, new tasks, new resources, new capabilities, and new issues."

How an organization manages and facilitates this process lies in the synchronization of cross-functional processes that feed into the submission process.

"By aligning all of the components and subprocesses with a common goal, the organization is able to discover efficiencies that span multiple functional areas," Mr. Walker says.

This alignment of processes is guided by four key principles that drive changes across the R&D organization: productivity and efficiency; compliance and quality; predictability and optimization; and flexibility and extensibility.

PRODUCTIVITY and EFFICIENCY

Every business function has the opportunity to become more efficient. The key to better productivity is easy access to data needed to perform functional tasks. Beyond this, automation of manual or high-volume tasks can furnish time for focus on higher value tasks.

"Efficiency is achieved once employees are able to seamlessly access, retrieve, and process data electronically," Mr. Walker says. "The outcome of any endeavor is predicated on an employee's ability to collect, manage, and deliver the right information to the right person at the right time. The goal is to eliminate overhead, rework, waste, and mistakes. All of these can be addressed at a process level to ensure repeatable gains."

Cost reduction has always been a central issue within pharmaceutical organizations. A reduction in costs is the result of providing lower factor costs and improved productivity.

"As processes are managed more effectively, resources are optimized, tasks and workflows are tightened, and issues are minimized or addressed more efficiently, this combination of factors offers incremental recurring savings," he adds.

COMPLIANCE and QUALITY

Organizations must commit to the development and documentation of processes and procedures to ensure consistent, repeatable, and reliable output. To do this, it is critical to define controls around critical steps in the procedure and enforce those controls.

"Process controls enable an organization to build compliance into activities so that final deliverables are accurate and timely," Mr. Walker says. "In the regulated environment of biopharmaceutical R&D, reducing the compliance risk is a competitive advantage."

Inherently, effective process management

should infuse quality into a process. By aligning processes with a common goal, rework and redundancies are minimized and areas for improvement are immediately recognizable.

"In this situation, a continuous feedback loop automatically incorporates performance improvements into existing standards of practice," he says.

IN AN EXCLUSIVE TO PHARMAVOICE, JIM WALKER, PRESIDENT AND CEO OF OCTAGON RESEARCH SOLUTIONS, EXPLAINS HOW PRODUCTIVITY AND EFFICIENCY, COMPLIANCE AND QUALITY, PREDICTABILITY AND OPTIMIZATION, AND FLEXIBILITY AND EXTENSIBILITY OFFER A STRONG FRAMEWORK FOR DESIGNING EFFECTIVE PROCESS MANAGEMENT.

PREDICTABILITY and OPTIMIZATION

Operational visibility and the generation of business performance metrics are key to both business agility and continuous process improvement. Visibility enables businesses to track, monitor, measure, and optimize processes in real time.

"In addition, it enables companies to recognize issues before they balloon into larger problems," he says. "Process visibility allows the organization to be opportunistic and identify trends that may impact the organization. By monitoring key performance indicators such as cycle times, response times, and employee output, an organization can use operational data to infuse quality into the entire process. This feedback loop enables benchmarking and dictates corrective action."

As various aspects of a process are optimized over time, metrics provide evidence of performance improvement and also may provide justification for a change in direction or a shift in a project plan.

It also is important to be able to assess the organizational impact of future events. Process simulation enables the business to assess processes prior to deployment.

"By modeling and analyzing potential approaches based on benchmarks and practical experience, organizations can deploy the most optimal processes," Mr. Walker says. "But effective simulation and modeling activities rely heavily on accurate assumptions and experience-based metrics."

FLEXIBILITY and EXTENSIBILITY

To support effective submission process management, business and IT alignment must become a reality. Migrating from a historical data perspective to a process perspective is an important point to consider.

"There is a fundamental change needed in the industry that requires business users with tools and technologies to become more self-sufficient in the management of the ultimate solution versus IT controlling the solution," Mr. Walker says. "This creates business self-sufficiency and empowers managers to act and react quickly to new forms of data. This flexibility is essential in complex processes that involve many resources with varying skill levels being assigned to multiple interdependent workflows."

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It is critically important for development teams, that are dispersed around the globe, to have insight into each stage of a product's life cycle.

Flexibility also offers a window of opportunity for managers to act on recent and relevant process data to avoid issues, alleviate bottlenecks, and minimize risk to a submission deadline.

"Process data often have an associated expiration date," he says. "If a manager cannot access process information in real-time, it automatically becomes a benchmark of past performance rather than an actionable indicator of present or future activities."

Traditionally, this type of information has not been available to dossier managers. Therefore, as the industry begins to focus on process management and transitions to a process-centric approach, it is important to prepare and train managers to accurately collect, interpret, and use process metrics. Incorrect assumptions and interpretations can lead to erroneous root cause analyses, ultimately resulting in continued and compounded inefficiencies.

Extensibility also is important, according to Mr. Walker, particularly from a technology perspective, because of the moving targets such as eCTD or SPL that the industry must embrace to remain competitive. Flexibility of information access and extensibility of the supporting technologies enable organizations to take control in a constantly changing environment. By controlling evolving processes and adapting technology to support new information perspectives, managers immediately will reap the continuing benefits of investing in a long-term process management approach.

Productivity and efficiency, compliance and quality, predictability and optimization, and flexibility and extensibility offer a strong framework for designing effective process management.

"Companies will benefit from considering these guiding principles when developing a process management approach and evaluating enabling technologies," Mr. Walker says.✥

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