



**Compliance: The New Driver for
Business Process Management**

Reader ROI

- Process compliance has become a key driver for employing business process management, in some cases eclipsing traditional process efficiency benefits.
- BPM serves as a tool set for ensuring adherence to SOPs for companies in regulated industries such as pharmaceuticals.
- BPM provides the ability to generate process documentation for demonstrating compliance in the event of an audit.

Compliance: The New Driver for Business Process Management

Vendors of business process management (BPM) products and services traditionally have responded to the most visible business process drivers—efficiency, effectiveness, and optimization. However, as companies have become more process-focused, compliance has emerged as a key challenge and as a driver for BPM.

Most companies have analyzed their business processes to achieve better, cheaper, faster solutions. Over time, companies have come to realize that better is more important than faster and cheaper.

Companies must comply with regulations and must be able to demonstrate compliance on demand. With executives now expected to personally attest to the accuracy of financial and audit documents, there is mounting pressure for tools that ensure adherence to processes.

How can BPM help?

At its most basic, BPM is a set of management practices used to understand business operations from a process-centric perspective. Business process management system refers to the software, platform, or suite of applications used to implement or support the BPM discipline. Once processes have been analyzed and modeled and standard operating procedures (SOPs) have been created, the focus is on ensuring that the SOPs are followed.

To date, this has been accomplished manually and reactively by way of training users on SOPs, submitting deviation forms when an SOP is violated, and conducting process audits. The obvious flaw in this approach is that there is no way to know whether deviation forms are being submitted accurately. Furthermore, these manual activities require significant resources and time.

BPM is already being used by many companies to automate business processes and drive efficiency. The value of BPM from a compliance perspective is two-pronged: ensuring that processes are executed per the company's standard operating procedures; and producing documentation to verify that adherence.

Process adherence

Although process adherence has not been a primary driver of BPM, it always has been an implied benefit. Once a company has analyzed and automated processes using a BPM tool, it has accomplished the first level of process compliance by deploying the process in a standardized way. In an automated system, users are limited to performing only the actions that are available. In systems which support role-based actions, an additional level of standardization ensures not only that users will take specific actions at each point in the process, but also that specific individuals are able to take only those actions that are enabled for them. This ensures, for example, that in the clinical development process, only an authorized person can resolve a data query or modify a key document.

Changes in standard procedures always raise concerns about whether the new processes will be followed. Support for role-based actions in an automated system lessens those concerns. In the event that an audit finding requires a process change, BPM simplifies the change. In this way, process standardization contributes to organizational agility.

Process documentation

Process adherence does not by itself satisfy compliance requirements. BPM takes it a step further by allowing management to produce process documentation that demonstrates what the process is, how it aligns with the applicable SOPs, and whether it was followed for a specific instance or transaction. This capability provides management with proof that processes are not only standardized and aligned to SOPs, but are being followed on a regular basis.

The process documentation capabilities of BPM can be configured to provide the desired level of detail required for each process. This proactively prevents compliance violations and makes documentation easily available in audit situations.

Process documentation is enabled by process metrics, which the BPM tool tracks for all process instances and transactions. This allows business activity monitoring, which consists of realtime dashboards that show process indicators such as percent of transactions requiring SOP deviations or volume of deviations by type. This level of tracking, coupled with a manager's ability to take action on specific transactions, brings process standardization and documentation full circle—driving process efficiency through tracking and codification.

Conclusion

While the value of BPM has been clearly demonstrated for efficiency-focused initiatives, ensuring process compliance is an emerging driver and a key benefit of the solution.

Though they may not necessarily generate immediate quantifiable returns, the BPM benefits of process compliance are tangible, and include:

- Reduced SOP deviations through process standardization
- Limit user actions to those appropriate to role
- Realtime process visibility and tracking to monitor process compliance
- On-demand documentation at the process level and transaction level
- Elimination of SOP deviation forms and process tracking forms
- Ability to easily modify the process in the event of compliance violation

In summary, BPM has a compelling value proposition and can provide a set of benefits to organizations interested in improving compliance and ensuring compliance documentation is available on demand.



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