Medical Device Manufacturers Put Quality Management at the Core of Their Global Business Processes

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No industries are as extensively regulated as those involving the manufacture of medical devices, pharmaceuticals, and biologic products. These manufacturers must prove their conformance with global quality standards to ensure patient safety, often forcing them to employ stringent and costly procedures. These procedures must be backed by in-depth documentation and reporting requirements. How can companies become more effective while meeting these critical regulations such as the Federal Drug Administration's (FDA) Quality System Regulation (QSR) or the pending implementation of the FDA's Unique Device Identifier regulations?

The real challenge facing life science companies is that meeting these extensive regulatory and quality procedures, codified in cGMP [current good manufacturing practices] regulations burdens companies, delays product rollouts, impedes innovation, and hinders business processes. What kind of innovation is needed for life science manufacturers to address these challenges and put quality management at the core of their business processes in a simple, cost-effective, and efficient manner?

The complexity of complying with cGMP controls can be reduced with advances in technology that can effectively integrate these procedures into a company's routine

business processes. Medical device manufacturers have long embraced enterprise resource planning (ERP) solutions to achieve operational efficiencies and manage their essential business processes. But now, by embedding cGMP process controls into routine processes, ERP solutions can ensure compliance by enforcing a specified workflow—optimized for efficiency and regulatory compliance. Integration will also allow quality processes to be used to enhance other areas of the business such as supply chain management. These processes extend beyond the typical quality assurance (QA) issues, encompassing areas such as supplier qualification, process development, documentation, distribution, service and repair or complaints. Integrating these quality processes and the information they generate into routine business operations can provide manufacturers with increased visibility into the performance of their supply chain partners, increasing efficiency as well as compliance.

Quality Management System (QMS) procedures such as CAPA (Corrective and Preventive Action) can be integrated to improve the overall efficiency and effectiveness of a company’s processes, thereby driving a total quality systems approach towards manufacturing operations. For example, required quality documentation can be automatically generated, with workflow routing for proper electronic signatures, etc., as part of the normal business process. Greater visibility is also gained from integration, as it can provide decision makers with a single point of view across operations, ensuring compliance and access to the information needed to make decisions impacting quality and business process efficiency.

Integrating quality procedures such as acceptance or in-process testing, including the ability to easily access the records and data can yield significant business benefits. Analysis of acceptance testing data may help with evaluating the quality record of a component supplier under consideration for recertification. It may provide critical information for a CAPA investigation. An ERP solution with automatically generated serialization for track and trace, can easily integrate and automate the inventory tracking requirements as specified in the QSR, which require the ability to identify products during receipt, production, distribution and installation. This capability has the added benefit of providing a medical device company with a global view across its entire supply chain. The ability to track a recalled item back to its manufacturing lot or batch and then forward again to locate distributed products that originated from the same source greatly enhances the visibility of a company’s entire supply chain. This can be achieved when serialization is integrated into an ERP system.

For example, the FDA’s Unique Device Identifier (UDI) regulations, poised to go into effect this year, can help companies innovate across their entire supply chain ecosystem above and beyond the obvious public health benefits. But, this can only be achieved if traceability functionality such as serialization, track and trace, is embedded in the ERP software and utilized throughout a company’s processes. The UDI system has the potential of providing companies better visibility into their distribution channels allowing them to improve trade activity management. When combined with the demand planning capabilities of an ERP system, it can help shed light on where and how their products are used, providing insights that may be used in brand management and even ideas for new product development.

When serialization functionality is integrated in an ERP system, it can enhance quality management by increasing the effectiveness of a recall and provide critical information for CAPA investigations. Suppose that a customer complaint led to a decision by a company to initiate a device recall. ERP serialization functionality integrated with the UDI will not only allow a company to recall the individual device, but also allow for a company to track the device back to its original production lot or batch. Then that same functionality will allow them to track forward through the supply chain to other potentially affected devices from that same production lot or batch, increasing the effectiveness of the recall.

Additional value can be realized since the original production lot or batch has been identified. The integrated quality functionality can be used to track back from the production lot to the components, raw materials, suppliers and specifications. This information will help pinpoint the source of the problem. QMS software integration can provide quick access to information such as documentation related to specification development or component and supplier selection, allowing that information to be accessed for use by any CAPA related investigations or processes. In contrast, many medical device companies may approach compliance with the UDI regulations as a labeling exercise. While this approach may ensure regulatory compliance, it won't provide the additional benefits that functionality integrated into daily business processes and driven by integrated ERP and QMS automation software brings to support brand and quality management.

Companies in the highly regulated medical device industry face a number of challenges from current and emerging regulations that directly impact their operations. Life sciences companies strive to become Effective Enterprises that meet the common goals of being patient focused, regulatory compliant and innovative. A medical device company can help achieve the vision of an Effective Enterprise by ensuring that its processes are well thought through, operating at peak efficiency and perfectly aligned with the strategic goals of the company. Putting quality management at the core of a company's business processes can greatly reduce the burden of compliance while enhancing the effectiveness of a medical device company's standard business processes.

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