Whitepaper

Medical Device Manufacturers Design Safe, Effective and Compliant Products with PLM

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Based on industry statistics, it is obvious that intensified regulatory scrutiny has become a harsh reality for medical device manufacturers. Over the last several years medical device companies have been hit with injunctions, undergone product recalls, or found themselves operating under Food and Drug Administration (FDA) consent decree. FDA regulations seem to impact every step of the medical device lifecycle from properly classifying a device and developing a regulatory strategy, to preparing FDA submissions. So, just how are successful medical device manufacturers cost effectively achieving compliance while at the same time meeting their product delivery targets?

Keeping the Pace: Technology is Key

Due to the fast pace of new technology, emerging market opportunities, and competition from start-ups, medical device executives find themselves in an environment where they must continually innovate with flawless execution to survive. They are discovering that next generation Product Lifecycle Management (PLM) systems may very well be the most valuable investment a medical device manufacturer can make for their medical device development process. Identifying a clear methodology and an efficient and cost-effective path through the medical device development lifecycle can increase a manufacturer's speed to market while ensuring compliance.

An inherent need to streamline business operations is driving more and more medical device companies to adopt PLM technology in order to be able to properly design safe, effective and compliant products. The mandates outlined in the FDA regulations related to medical device development protocol such as Part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11) and 21 CFR Part 820 Quality System cover everything from device design and manufacturing to training and installation, to processing inquiries and/or complaints.

Meeting the requirements of CFR Part 11 and Part 820 regulations can determine the success or failure of a medical device manufacturing company. To be compliant with the Part 11 regulations, manufacturers who track their documentation electronically must meet the electronic records and electronic signature guidelines set forth by the FDA. Part 820 requires manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of finalized medical devices. Clearly these regulations require exceptional information management techniques and can offer a daunting challenge to manufacturers, many of which have traditionally relied on manual or semi-automated solutions to manage product development. Attempting to manage and access this information in a paper-based fashion can prohibit medical device manufacturers from adequately complying with FDA regulations.

As a central database, PLM manages the numerous Bill of Materials (BOMs), engineering changes, parts and associated documents created during the design process. Medical device manufacturers can easily maintain, access, and report on required information such as a Device Master Record (DMR), Design History Record (DHR) or Design History File (DHF). In following CFR Part 11 guidelines for managing information electronically, PLM technology can support the required password protected signoffs, authorized electronic signatures, and history tracking for complete electronic audit trails. Security features to control accessibility to information such as defined user roles address security guidelines. Additionally, next generation PLM systems typically offer quality management and training records management capabilities which support requirements for meeting Part 820 Quality System guidelines. The ability to manage the complete product record within in single environment and address quality system requirements with PLM can save device manufacturers time and money by streamlining the entire product development process and eliminating the need to invest in separate systems.

Case in Point

A leading innovator of endovascular treatments for Peripheral Arterial Disease (PAD) and maker of a device that clears out blockages in clogged leg arteries can attest to the benefits of PLM technology for medical device manufacturers. Having an experienced staff that worked in previous medical device start-ups, the company was well versed in the benefits of a PLM system to support their product development efforts. The medical device manufacturer implemented a PLM solution in order to streamline the entire engineering change process, implement better control with document vaulting, improve Bill of Material (BOM) management, and make product information (drawings, blueprints, revisions, and supporting materials) easily yet securely accessible to appropriate team members.

All departments that have governing procedures are using the PLM system including: design engineering, quality, regulatory, manufacturing engineering, purchasing operations, and even facilities management. Document control, engineering change, BOM, and regulatory conformance processes are managed via the PLM system as well as any changes made to any procedures. This level of automation makes their process more efficient and provides a better documentation trail for auditors and compliance mandates.

Simplifying the Audit Process

Medical device manufacturers are required to have formal processes in place to manage data for all facets of design and development such as: change control, supplier management, corrective and preventive actions (CAPAs), inspection, and test procedures. In addition, evidence must be

presented that formal processes are being adhered to. Not only can a system that provides traceability and clear tracking of procedures and sign offs facilitate this, it's the law.

PLM technology delivers a controlled environment for managing and tracking product data through automated processes, which is critical to achieve compliance. The visibility into the complete product record and managing of all product information within one environment certainly helps to ease the audit process. In the case of the medical device manufacturer, the company is required to meet International Organization for Standardization certification (ISO 9001:2008 international standard). ISO auditors check to see how a company manages its product documentation, change orders/change management, and engineering processes. Prior to automating with a PLM system, the company would have to show and explain its manual process, walk an auditor through all of their documentation, and search for requested documents in folders and file cabinets – a cumbersome project.

Adopting a PLM system to centralize all product related information and properly track data allows medical device manufacturers to easily find required information for auditors, generate custom reports as needed and prove out their processes. PLM systems make all this required information available at a person's fingertips to be easily presented to auditors.

The Bottom Line

Rapid industry growth, competition, the regulatory environment, and an inherent need to streamline operations are driving more and more medical device manufacturers to adopt technology solutions like PLM. The bottom line for medical device companies trying to compete in today's high-tech world is that adopting new software technologies is no longer a luxury or superfluous to a company's success—but, rather, an essential key to success in an industry that has become overwhelmingly competitive and regulated.

Omnify Software is a leading provider of business-ready Product Lifecycle Management solutions for medical device manufacturers. For more information, visit www.omnifysoft.com

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