Medical Device Manufacturers Address Compliance Mandates with Product Lifecycle Management

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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 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

The Millennium Research Group [1], a global authority on medical technology market intelligence, anticipates that device manufacturing executives will rely on technology solutions to overcome some of these regulatory burdens and save costs in hopes of recuperating lost profits from the Patient Protection and Affordable Care Act of 2010's addition of the excise tax on medical devices.

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 turning to their IT gurus and engineering architects for technology solutions and 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. According to Frost and Sullivan's [2] Industry Analyst Saju John Mathew, "What is key is that the right steps are taken at the right times and are properly documented for FDA compliance and approval, avoiding the need to repeat phases—a misstep that can be extremely costly in both time and capital—and can throw a medical device manufacturer way off course."

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 (BOM), 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, Design History Record, or Design History File. Additionally, 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. Lastly, 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 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: The Pathway to PLM

One such company, Pathway Medical Technologies [3], a Kirkland, WA-based innovator of endovascular treatments for peripheral arterial disease (PAD) and maker of a device that clears out blockages in clogged leg arteries uses PLM technology and received FDA 510(k) clearance in 2009 to market its JETSTREAM G3 peripheral atherectomy catheter for use in the treatment of PAD in the lower limbs (below the knee).

Ken Perino, senior director of quality assurance and regulatory compliance at Pathway Medical Technologies, was the one to spearhead Pathway's initiative to automate their product development process. Having worked in previous medical device start-ups, Perino had become well versed in the benefits of a PLM system to support his efforts. He implemented the Empower PLM solution from Omnify Software [4] in order to streamline the entire engineering change process, implement better control with document vaulting, improve BOM management, and make product information (drawings, blueprints, revisions, and supporting materials) easily yet securely accessible to appropriate team members.

His advice for other medical device companies is that they should look for PLM solutions that are easy to use, fast to deploy, and very affordable without skimping on essential PLM functionality. Too often, the biggest problem with many PLM tools

on the market is that they have become more complicated without becoming more functional. It is very difficult to solve a complex problem with a complex tool and a much better solution is choosing a PLM approach that is straightforward. At Pathway Medical, document control, engineering change, BOM, and regulatory conformance processes are managed via the Omnify Empower PLM system. All departments that have governing procedures are using the system, including design engineering, quality, regulatory, manufacturing engineering, purchasing operations, and even facilities management. Any changes made to any procedures are performed and managed within the PLM system.

“Gone are the days that a physical folder is being passed around and emails flying around in regards to where the folder is in terms of going through the different teams for an engineering change,” said Perino. “Because Omnify completely automates our process, when you submit your engineering change for review, the system sends it out to everyone who is a signer or observer in parallel and the engineering team can view engineering changes in real time.” This level of automation not only makes Pathway Medical’s process more efficient but also provides a better documentation trail for auditors and compliance purposes.

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 Pathway Medical, the company is required to meet International Organization for Standardization (ISO) certification (ISO 9001:2008 international standard). ISO auditors check to see how Pathway (or any company they are auditing) manages its product documentation, change orders/change management, and engineering processes. Prior to automating with a PLM system, Pathway Medical 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 like Pathway 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 to a person’s fingertips and can be easily presented to auditors.

Successful Strategies

What is top of mind today among medical device manufacturers is the need to attain a better understanding of which strategies are being successfully used to

ensure device quality in the face of regulatory uncertainty. Cambashi [5], a leading global industry analyst and market consulting firm, sees that while the global market and supply base for medical device manufacturers offer new opportunities for innovation and growth, it also brings new challenges for keeping costs and risks low, especially in areas such as R&D, sourcing, manufacturing, quality assurance, regulatory compliance, supply chain, and financial operations. Cambashi has conducted a study to identify the major challenges to and approaches for balancing innovation, cost, growth, and risk among medical device companies and their trading partners. It explores whether companies are deploying the strategies that regulators suggest and the information systems to support them. It aims to outline practices and systems medical device companies should consider to ensure optimum throughput and quality.

Compliance Dynamics [6], a services company specialized in helping medical device companies with their business management system, operational, and regulatory compliance needs, knows this well and has been helping medical device companies navigate their way around these obstacles through the use of sophisticated systems and technology. “It’s no-longer just about proving to the FDA that your company has effectively addressed the required (regulated) processes, but that you’re a sound run business as well. This is where a solid PLM system implementation can shine. The FDA has made it clear that they want companies to fulfill the regulatory requirements while demonstrating they can be successful as a business. After all, having a medical device in the market and the manufacturer out of business is a loss-loss for all parties involved,” said Roger Martin, president of Compliance Dynamics.

Conclusion

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.

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