Emphasis on QA/QC Streamlining Quality Assurance and FDA Compliance

AT A GLANCE

- CARs and CAPA defined
- 21 CFR Part II initiatives
- Part 820's GMP regulations
- DHR and DMR examined

Medical device companies are transforming regulatory compliance from a disparate set of cost center activities to a core element of their profit-focused product initiatives. This report explains how PLM can help companies obtain higher margins on their products and avoid risks arising from non-compliance with FDA regulations.

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By Mike Adami-Sampson

The medical device industry is unique from most other discrete manufacturing industries due to its high degree of government regulation and the need for proactive self-monitoring related to product quality. Medical device companies must constantly interact with physicians, surgeons, and patients to monitor and report the success and failure of installed products in the field&#151sometimes over years of use. In addition, medical device customers (hospitals, care providers, physicians) must adhere to government regulations by issuing Corrective Action Requests (CARs) to manufacturers when they detect a device defect. In turn, manufacturers must report such defects to the Food and Drug Administration and submit plans for Corrective Action/Preventive Action (CAPA) to ensure that such defects will be remedied and eliminated during future production.
Some of the most stringent requirements are outlined in Parts 11 and 820 of Title 21 of the FDA's Code of Federal Regulations (CFR), which are being addressed by many of the most successful medical device companies with electronic-based systems for quality assurance and regulatory compliance.

Complying With Regs

Title 21 CFR Part 11 provides guidelines for the FDA's acceptance of electronic

records and electronic signatures in lieu of paper records and handwritten signatures. While the FDA does not mandate adoption of 21 CFR Part 11, medical device companies that transform their organizations from paper-based to electronic systems greatly reduce quality assurance and compliance process time as well as the risk of FDA non-compliance caused by human error. As a result, these companies can get swifter regulatory approval.
Medical device companies undertaking 21 CFR Part 11 initiatives have found that doing so also sets the stage for improved compliance with 21 CFR Part 820 Quality Systems Regulations, also known as Good Manufacturing Practices (GMP). This is because Part 11-compliant organizations have already established the processes and organizational controls for restricting access to electronic records, controlling distribution of documentation, maintaining audit trails, and defining accountability of individuals.

Unlike Part 11 compliance, Part 820's GMP regulations are mandatory. Since 1978, Part 820 has specified rules for the manufacture, packing, storage, and installation of medical devices. The Safe Medical Devices Act enacted in 1990 provided the FDA with the authority to add pre-production design controls to the GMP regulations, which the FDA enacted in 1997.

The addition of pre-production design controls information poses a significant challenge for medical device companies that do not capture information electronically. Pre-production design has traditionally followed less stringent processes, often combining science, art, conjecture, and ad hoc collaboration. These activities do not occur in clearly delineated phases and thus could hamper Part 820 regulatory compliance efforts. In fact, the FDA amended Part 820 to include design controls following a six-year study, which found that 44 percent of voluntary device recalls occurred as the result of faulty pre-production design controls.

Achieving a combined strategy of Part 11 and Part 820 compliance requires companies to establish a single, unified environment for tracking all product-related information as products pass through their lifecycle of design, development, clinical trial, manufacture, service, and retirement. The adjacent chart, "Managing Medical Device Product Lifecycle for Regulatory Compliance," depicts the medical device product lifecycle as well as the information, processes, and controls that need to be managed at each stage to achieve Part 11 and Part 820 compliance.

Single Information Environment

To provide for the storage, access, handling, and sharing of product-related information in these various areas, a growing number of medical device manufacturers are using a new class of enterprise software known as Product Lifecycle Management or PLM. Using this technology, companies can manage all information about their products, from initial concept through to manufacturing and after-market service, within a single information environment that ties together all product-related processes, data, and non-product documentation across a company's value chain of customers, employees, partners, and suppliers.

PLM incorporates all elements of product data, from original CAD designs to Bills of

Materials (BOMs) to manufacturing inspections, and ties that data to the critical processes and tasks that numerous internal and external teams undertake to develop and bring products to market. The technology addresses the complete medical device product lifecycle, enabling companies to seamlessly incorporate quality assurance and regulatory compliance into each lifecycle phase so that quality and compliance become core elements of profit-driven activities.

Solution of Choice

PLM is becoming the solution of choice for medical device companies seeking to migrate to electronic records and signatures from hand-written documentation. Why? Because PLM provides the critical functionality needed to centralize, share, audit, and protect all electronic product data and electronic signatures. In addition, the security built into PLM allows companies to take advantage of 21 CFR Part 11 without being victimized by fraud or unauthorized data access.

For years, companies of all sizes, such as GE Medical Systems, Medtronic, Possis, and Calypso Medical, have leveraged their PLM environment to enable quality assurance programs and to achieve Part 11 and Part 820 compliance as they drive new products to market.

PLM software provides a single, unified information environment for all product data, and some vendors have even developed specific templates and business rules for managing product development processes according to FDA regulations.

Templates are provided for Phase/Gate design control (β820.30 Design controls) procedures that manage the design process. All project deliverables (documents, decisions, discussions approvals, etc.) are linked to the tasks. So when a deliverable is updated, the task is automatically updated, resulting in a clear documentation of responsibilities and actions within a project.

Using this information, the system automatically updates the Device History Record (DHR) required by β820.184. Users can easily and quickly find all relevant product records and their Part 11 compliant electronic sign-offs and can trace all activities that occur&#151with assigned responsibilities, handovers, discussion threads, and ad hoc processes.

The system also supports information handling requirements for Device Master Records (DMR) in compliance with FDA standard 21 CFR Part 820 including device specifications, production process specifications, quality assurance procedures, packaging and labeling specifications, and installation, maintenance, and servicing procedures. The system also maintains all product-related files, data, and records to form an audit trail that documents all product changes including comments, approvals, revision history, and justifications for the change.

The CAPA process is supported by linking actions to the actual information that they address. Because the CAPA system and processes exist within the same environment as a company's product data, CAPA actions link directly to Change Requests, Change Orders, DMRs, and any other document or procedure that is

affected by the CAPA process.

Summary

The notion that medical device companies must maintain robust quality assurance systems to achieve regulatory compliance is not a new one. What is new, however, is the opportunity for medical device companies to transform regulatory compliance from a disparate set of cost center activities to a core element of their most strategic and profit-focused product initiatives.

Numerous medical device companies are leveraging collaborative PLM solutions to drive profits through faster time-to-market and streamlined quality assurance and regulatory compliance. Through a single information environment that ties together all product-related data and non-product documentation, medical device companies are earning higher margins on the products they deliver and insulating themselves from costs and risks arising from non-compliance with FDA regulations.

ONLINE

For additional information on the technologies discussed in this article, see *Medical Design Technology* online at www.mdtmag.com or MatrixOne Inc. at www.MatrixOne.com.

Managing Medical Device Product Lifecycle for Regulatory Compliance

Concept

&#149 Capture updated customer requirements and marketing data (i.e. demand, market size, market segments)

&#149 Leverage internal intellectual property

&#149 Incorporate quality assurance information from past development efforts

Design

&#149 Incorporate FDA and other regulatory requirements into the design process

&#149 Manage product specifications

&#149 Collaborate internally and externally on product design

&#149 Involve strategic suppliers for prototype development

&#149 Develop product quality assurance documentation aligned with regulatory requirements

Clinical Trials

&#149 Monitor and report product defects

&#149 Monitor and report overall product quality and effectiveness

&#149 Communicate quality issues

&#149 Communicate Corrective Action Requests (CARs)

Product Launch

&#149 Collaborate to rapidly implement changes in response to CARs and manage performance and cost

&#149 Accelerate NPI process via efficient change management and communication

&#149 Eliminate excess scrap and re-work

&#149 Manage regulatory submissions, approval processes, and documentation

Production Ramp & Volume Production

&#149 Implement final design changes

&#149 Synchronize suppliers with final design and product requirements

&#149 Manage manufacturing across all locations

&#149 Communicate quality issues and CARs inside and outside the enterprise

&#149 Manage closed-loop Corrective Action/Preventive Action (CAPA) processes

&#149 Manage suppliers and manufacturing to drive out costs

&#149 Manage post-market surveillance

Service & Retirement

&#149 Maintain easily accessible and secure product information

&#149 Maintain complete audit trail of all product development and production

&#149 Communicate product quality assurance back to New Product Development

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