ABSTRACT

Medical device manufacturers face the same intense competition that other FDA regulated manufacturers face, but with the added burden of having to plan, develop, test and produce in an environment rigidly controlled by regulatory requirements.

To meet regulatory mandates, medical device manufacturers must be able to provide, upon request, documentation supporting the entire product lifecycle, from concept through execution. For many companies, this means maintaining hardcopy records of all related product information. And with a paper-based system of record-keeping, this requirement adds a huge burden to an already formidable task.

With an electronic system of record-keeping, medical device manufacturers could ease this burden by streamlining processes to drive innovation. By using an electronic system that automates the task of capturing records, companies can focus on innovating and accelerating time-to-market.

This white paper describes how you can ‘hardwire’ regulatory compliance to improve performance of critical business processes including quality systems management, change management and requirements management to drive innovation.
Introduction

In today’s global marketplace, manufacturers are faced with intense competition, which is driving a demand for innovation, faster time-to-market, and lower price premiums. Consequently, manufacturers must develop higher quality products faster and at a lower cost. Medical device manufacturers face an even larger challenge by having to comply with strict regulatory requirements. Compliance requires that every decision and every step of the process be tracked and recorded, which adds a huge burden to medical device manufacturers trying to remain competitive. FDA-required design controls force companies to integrate quality systems regulations with product development.

For many medical device manufacturers, the process of keeping paper-based records adds to an already significant burden. And while most of the files that must be recorded for regulatory purposes are created and stored electronically, unfortunately, they reside in disparate locations. Without a secure, central electronic repository to manage these documents, hardcopy records must be stored and managed in a single location to ensure that all the records can be found if requested during an audit. Therefore, resources are required to print these documents, fill out and attach relevant forms, and file them in the proper locations.

Not only is this process slow, but it is also costly in terms of the amount of time spent filing and searching these records. Searching through filing cabinets and binders to find requested information during an audit is an arduous process. It provides many opportunities for errors in misfiling, tagging records incorrectly, or recreating information that already exists because it can’t easily be found.

Furthermore, the burden of keeping up with regulatory compliance, while getting life-saving products to market as quickly as possible, leaves companies with little time to focus on moving from paper-based to electronic-based record-keeping. Ironically, it is this very shift that could enable those same manufacturers to make their regulatory compliance processes less burdensome and more automatic, so they can focus on developing innovative products faster and more efficiently.

An electronic-based system of record-keeping can help manufacturers ‘hardwire’ compliance into their systems by automating the process of capturing records. While the biggest benefit of this is ensuring better audit results, electronic record-keeping also benefits other areas of product development including change management, requirements management and quality systems management. In the following sections you’ll see how an automated, electronic system can aid in detailed design to improve audits, accelerate time-to-market, and gain competitive advantage.

21 CFR Parts 820 & 11

Medical device companies that want to sell products in the United States must first be granted permission by the US Food and Drug Administration (FDA). To obtain permission, companies must comply with several laws from the US Code of Federal Regulations (CFR), the most prominent of which is 21 CFR Part 820–Quality Systems Regulations.

Part 820 defines the important concepts of design control and quality records. Under this regulation, medical device manufacturers are required to document the entire design process from cradle-to-grave. To be compliant, companies must create a Design History File (DHF) comprised of the following sections:

- Design planning
- Design inputs
- Design outputs
- Design reviews
- Design verification
- Design validation
- Design transfer
- Design changes

The FDA does not require that medical device companies keep these records electronically. However, most companies realize that to be a player in today’s globally competitive environment, they must continually reduce time-to-market. And the most effective means of doing this is to implement electronic records and signatures. Another important FDA regulation–21 CFR Part 11–describes the measures companies must take to assure the accuracy, security and authenticity of electronic records and signatures. Software used in the implementation of a medical device manufacturer’s quality system is specifically mentioned as being subjected to the requirements of 21 CFR Part 11. Therefore, product development and quality systems must be integrated to satisfy both 21 CFR Part 11 & Part 820.

Together, 21 CFR Part 820 & Part 11 can pose significant challenges to companies in their quest to accelerate innovation. In the following sections of this white paper, you’ll discover how these same regulations present an opportunity for companies to ‘hardwire’ compliance, and convert quality from a cost of doing business to a competitive advantage.
Regulatory Compliance

It is impossible for medical device manufacturers to conduct business today without paying close attention to regulatory compliance. FDA regulations introduce increasing complexity into internal business processes, delaying the pace of innovation and new product introduction. And it’s expensive too, with the cost of compliance now estimated at 2% of revenues. The expense, however, pales in comparison to the potential cost and risk of non-compliance.

Regulatory issues confronting medical device manufacturers include:

- How do I ensure all required records and documents are captured, managed and stored according to FDA regulations?
- How do I validate that processes meet regulatory requirements?
- How can I streamline and automate my paper-based processes?
- How do I comply with new regulations—before they are mandated?
- How do I respond to FDA requests with the required documentation, in the right format, as quickly as possible?

Benefits of an Electronic Process for Regulatory Compliance

Investing in a scalable, enterprise compliance solution can have significant top-line and bottom-line benefits that extend well beyond simply achieving compliance, including:

- Reduced time-to-market through faster product development and regulatory approval
- Improved product development productivity
- Reduced costs in compliance analysis, reporting and approval
- Reduced cost of recycling
- Reduced safety risk and cost of litigation due to non-compliance

Quality Management Systems

Quality systems management presents unique challenges for medical device manufacturers because, in addition to the many quality challenges that face all manufacturers, they also have to meet strict regulatory requirements in their quality systems. This burden can add significant overhead to quality systems, making it even more difficult for medical device manufacturers to remain competitive.

In an environment tightly controlled by regulatory requirements, medical device manufacturers must be able to demonstrate that disparate quality management systems and procedures are executed consistently across the enterprise. To comply, many companies try to force these disconnected systems to integrate, but this creates additional challenges in managing separate systems that must communicate with one another.

Maintaining separate systems also makes it more difficult to capture lessons learned and facilitate process or performance improvements across the enterprise. During audits, the weaknesses of a paper-based system become painfully clear when companies need to show that they follow current GMP (Good Manufacturing Practices), capture quality system metrics, maintain proper documentation, effectively train personnel, ensure compliant change control, and perform regular internal audits. In a paper-based system, accessing the documentation to support these requirements is a completely manual process and can prove to be a significant challenge.

Benefits of an Electronic Process for Quality Management Systems

An integral, electronic process for quality management system can help you reuse knowledge across your enterprise, facilitate collaboration, create a competitive advantage, and improve audit results. Typical benefits of moving from a paper-based to an electronic quality systems management process include:

- Increased innovation—By improving the ability to capture and share lessons learned across the enterprise, improvements are continually built into processes resulting in more time to focus on innovations instead of fixes.
- Improved collaboration—By providing simultaneous electronic access, design partners can collaborate across distances, time zones and even companies.
- Better compliance—Achieve closed loop, compliant change control that automatically tracks the results of personnel training, internal quality audits, and quality system metrics.

Better audit results—Find and access audit documentation more efficiently. Automated compliance processes ensure that the documentation is compliant and complete.

Business Intelligence Solutions

The Building Blocks to Better Business
Change Control
Many companies today are challenged by change control procedures because the process is manual and paper-based. As a result, change control can be very slow and error-prone.

According to 21 CFR Part 820.40 section D, changes to a document or engineering drawing must be reviewed and approved by personnel with the same functional responsibility as the original approver. From there, the changes must be communicated to all appropriate personnel. Lastly, companies must maintain a complete audit trail of the change, review and approval process.

Changes are often captured manually by red-lining a hardcopy of the design documentation. This manual process provides opportunities for errors via misinterpretation and omission whenever changes are made to the source document or drawing. As a result, the downstream documentation may be incomplete or incorrect, and critical design aspects and configuration history records are lost, which not only causes problems in downstream product development stages, but also adversely affects audits.

The change control process is further complicated by companies using multiple systems to store and manage product information, as well as the fact that paper-based records are notoriously hard to search. As a result, companies find it difficult to find, analyze, monitor and provide status of change information. Furthermore, during review processes, not everyone will have access to the records they are supposed to review.

As product complexity, variants and options increase, so too does the need to manage change and product configurations. Inadequate configuration management practices make it difficult to capture important product milestones, track incremental product updates, and make updates to configuration impacted by change.

Benefits of an Electronic Process for Change Control
- Improved productivity—Employees can spend more time focusing on product development rather than administrative tasks associated with change management record-keeping.
- Better compliance—An electronic process provides automated tracking and linking to ensure better audit results.

Requirements Management
The capture and management of requirements is challenging for many medical device companies because requirements are typically managed manually using paper-based documents that are disconnected from the rest of the product design data. Managing requirements manually using unconnected documents makes it difficult to manage individual requirements discretely. Product managers and system engineers spend too much time building and maintaining manual traceability matrices, which quickly become out-of-date, resulting in a lack of visibility to customer needs during product development—a major regulatory violation.

Regardless of where requirements are managed, it is most important to get the ‘right’ requirements from customers, and to get the requirements ‘right’ in your product designs. Without the ability to effectively communicate requirements and to facilitate collaboration between stakeholders, marketing, and engineering, it is difficult to validate that the product development team correctly understands customers’ needs and that underlying designs serve to meet those needs.

Benefits of an Electronic Process for Requirements Management
- Increased market success—Making requirements accessible to the entire product development team ensures collaboration, better validation, and a greater focus on customer needs.
- Higher quality products—Traceability of requirements through product development improves the impact assessment of design changes.
- Better compliance—Changes are always linked to the original records, ensuring that when changes are made, all associated records are automatically updated. Accurate records and traceability of requirements through product development ensures better audit results.
Managing Design History Files and Device Master Records

The Design History File (DHF)—a compilation of records describing the design history of a finished device, and the Device Master Record (DMR)—a compilation of records containing the procedures and specifications for a finished device, are required by the FDA in 21 CFR Part 820. These requirements create a huge burden for device manufacturers as they have to ensure that every design decision, every change, and every process is captured and documented.

In a paper-based system, a significant amount of time is dedicated to maintaining DHF and DMR records. Decisions must be documented and linked back to original requirements or to downstream processes. However, because this is a manual process, it is very difficult and time-consuming to capture the reason behind all design decisions. As a result, it is not uncommon for important product design information to be missed. In addition, records can be misfiled, information may be changed incorrectly, and often entire records go unfiled.

Benefits of an Electronic Process for Managing Design History Files and Design Master Records

Most of the files that make up the DHF and DMR are created electronically. Filing them in a paper-based system creates an additional burden on workers. In an electronic system, files are stored in a central repository rather than in disparate file systems (See Fig. 1). DHF and DMR information can be automatically captured when files are checked into the repository in an ordered approach using a hierarchical folder structure. Furthermore, files are automatically linked to relevant records, ensuring all records are accurately captured. This process also provides full traceability, from design through production.

Typical benefits of moving from a paper-based to an electronic DHF and DMR process include:

- Improved productivity—By automating the filing of records and enabling easy electronic searches, workers spend less time filing and searching records, and more time developing products.
- Better compliance—By automating the filing of DHF and DMR records, you ensure that all records are captured, changes are accurately made to all relevant records, and all required records are easily accessible. All of this leads to faster FDA approval and better audit results.
- Faster time-to-market—Automating processes and hardwiring compliance ensures that you get your product to the marketplace faster, where it can start helping customers sooner and generate important revenue earlier.
- Track the status and ownership of all requirements deliverables for every process milestone with deliverable management capabilities
- Implement an out-of-the-box change and configuration management process with support for informal and formal changes
- Gain instant access to change information for analysis, review, approval and implementation with an automated, closed-loop process
- Describe, classify and prioritize Problem Reports and Enterprise Change Requests
- Document, review and approve change business justification, impact and analysis
- Effectively plan and manage change implementation using Engineering Change Notices
- Support real-time change tracking, audit history, electronic signatures and statistics

Summary

In the medical devices industry, competition is fierce and delays are costly. Anything companies can do to improve and accelerate audit results provides them with a competitive advantage. Furthermore, by locking in regulatory compliance, device manufacturers gain valuable time to build innovation and quality into their product, furthering the competitive advantage.

Unfortunately, many companies are still using paper-based systems to manage records for regulatory compliance, which significantly slows down the regulatory process. The amount of time required to capture and, later, find relevant records leaves little room for process improvement.

With an electronic-based system, medical device manufacturers can hardwire compliance into their processes to accelerate innovation. Tasks such as capturing records required for regulatory compliance, linking design outputs to requirements inputs, and updating related records when source information changes, are all automated. This allows companies to free up their workers to concentrate on developing innovative solutions to customer requirements.

Automating manual tasks results in higher productivity, which in turn, leads to faster time-to-market and greater profit margins. All these capabilities lead to a competitive advantage in a fiercely global market. An automated quality management system provides an organization with the tools to streamline the end-to-end quality management process.

With automated change control, the quality managers have visibility into the status of any change request at the click of a mouse - who has reviewed the revised document, who is sitting on the approval request and needs to be prodded and who else needs to review it. As a result, review cycle time can drop by as much as 50% after the process is automated. Once approved, the new version automatically replaces the existing version of the document making change control a very smooth process.
Professional and Technical Services

Business Intelligence Solutions specializes in providing a full scope of regulatory software products and professional services to medial device, pharmaceutical and biotechnology companies.

As a regulatory compliance specialist, our expertise is in designing, integrating, supporting and validating regulatory processes with the purpose of accelerating innovation.

Clinical Affairs Solutions

FDA Consultants will immediately supplement your organization by providing various clinical affairs solutions, including planning and executing clinical trials that will withstand the review and scrutiny of the authorities including the FDA and International Regulatory Authorities.

Compliance Solutions

Audits - Our Consultants are recognized as expert third-party auditors. We provide the correct balanced and perspective by providing both industry experts and former FDA Investigators to perform audits.

Quality System Solutions

FDA Consultants will immediately supplement your organization to provide quality system solutions, which will comply with FDA and the appropriate International Regulatory Authorities regulations and standards.

Regulatory Affairs Solutions

FDA Consultants will immediately supplement your organization to provide various regulatory solutions, including various product dossiers and submissions for review and approval by the authorities such as FDA and International Regulatory Authorities.

Training Solutions

FDA Consultants provides both on-site and webinar, customized personnel and management training for the FDA regulated industry both in the United States and abroad.

Business Intelligence Solutions offers very practical steps on how to implement some of the sweeping changes in the mindset of medical device executives require, in bite-sized steps.

Contact us today at info@busintellsol.com to receive the Five Strategies to Reduce FDA Enforcement Guide.

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