Moving from Paper to Electronic Records: Hardwiring Compliance into Product Development

Using technology to incorporate quality system regulation

Abstract

Medical device manufacturers face the same intense competition that other 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 and automating record-keeping. By using an electronic system that both links Product Development and Quality System Regulations, and automates the task of capturing records, companies can focus on innovating, accelerating time-to-market, and improving their audit results.

This white paper describes how you can 'hardwire' compliance into your product development processes with a validated system that automatically captures required records for regulatory purposes. In addition, you'll learn how such a system improves performance of several critical business processes including regulatory compliance, quality systems management, detailed design, change management and requirements management. Lastly, you'll get an overview of PTC's Product Development System, which helps leading medical device manufacturers to automate compliance and gain a competitive advantage.

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 product development. 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 Systems Management

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 Systems Management

An integral, enterprise system for product development and quality system management 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.

Hardwiring Compliance in Detailed Design

Detailed design is the process of fully defining product design so that it meets specific requirements and is sufficiently documented for manufacturing. For medical device manufacturers, this process is further complicated by the need to implement design controls (per 21 CFR Part 820.30), which not only requires design outputs be documented, but cross-functional design reviews, design verification and validation processes as well.

Companies are required to keep records of all design decisions within the Design History File and be able to trace them back to the original design requirements. This means manufacturers must be able to match every design output to a requirements input. Manufacturers must be able to demonstrate, through the records they keep, that every design decision or change satisfies customer requirements. And, if the requirements change, companies must be able to show how and why those requirements changed.

Many of the components of the Device Master Record (DMR), including product and process specifications, QA procedures and acceptance criteria, are developed during the detailed design process. As with the content of the DHF, personnel must have fast access to all pertinent documentation as well as the genealogy of the final documents.

Most detailed design documentation is created electronically in CAD programs or in common desktop applications. In a paper-based system, however, the act of capturing these records to comply with regulatory requirements is a separate step from creating the records, which creates an additional burden on workers and slows down product development. Furthermore, it's a process where errors are easy to make and hard to find.

In an electronic system, the design record is automatically captured as part of the file creation process. The ability to link relevant information is built into the system rather than being a separate manual process. This enables all associated information to be linked together. For instance, design inputs and design outputs are automatically linked so you can be sure you have satisfied all your design criteria. The "document of record" can be easily identified.

Not only are records automatically captured and linked, but an electronic system makes it easier to find existing information. With electronic searching capabilities, you can quickly and easily find information you need. You can also reuse that information in such a way that if changes are made to the source materials, all instances of that information are automatically updated in real time. This capability relieves your staff of the huge burden of manually finding and updating all instances of the information, and helps ensure that your documentation is accurate and up-to-date, resulting in better audit performance.

By automating many of the tasks required for regulatory compliance, you can 'hardwire' compliance into your system. Rather than being a process that's separate from product development, compliance is built in, allowing you to focus on improving innovation, quality and performance.

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

A flexible, responsive and efficient change control process improves a company's ability both to compete and to automatically comply with regulatory requirements. Typical benefits of moving from a paper-based to an electronic change control process include:

- Increased innovation–By reducing the change-related administrative workload, you provide more engineering time to develop innovative products.
- Higher quality products–By minimizing errors and maximizing the ability to identify and introduce changes earlier in the process, you reduce manufacturing issues and raise the overall product quality across the product lifecycle.
- Reduce time-to-market–Eliminating time-consuming manual tasks reduces product development cycle time.
- 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

An integral requirements capture and management process provides visibility into customer needs throughout the entire product development lifecycle. Typical benefits of moving from a paper-based to an electronic requirements management process include:

- 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.

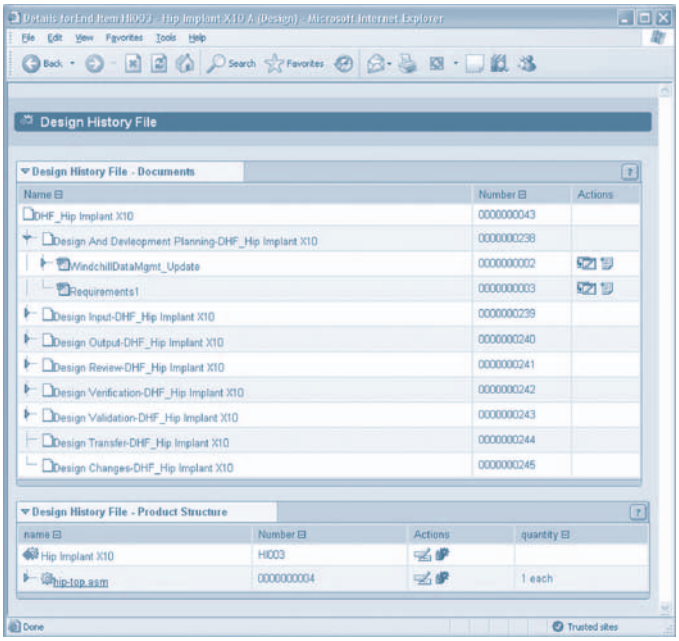


Fig. 1. The Design History File is a compilation of all documents and changes that describe the complete design history of a finished product.

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

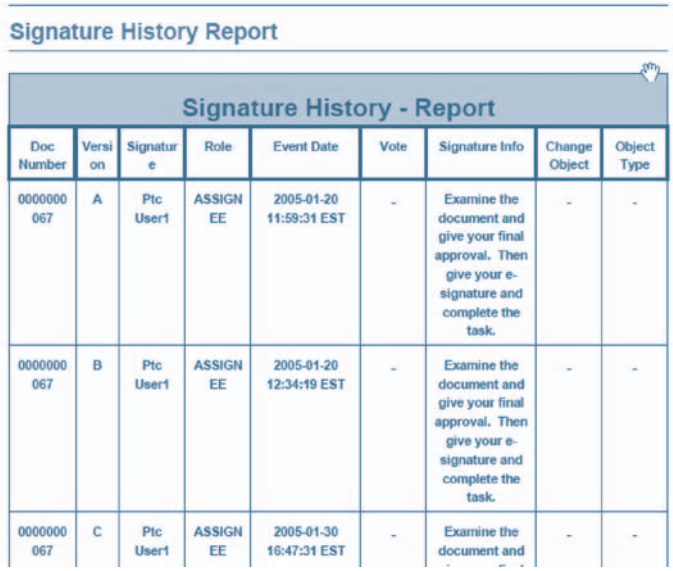
Most of the files that make up the DHF and DMR are created electronically. Filing them in a paper-based system creates an additional burden on workers. In an electronic system, files are stored in a central repository rather than in disparate file systems (See Fig. 1). DHF and DMR information can be 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.

PTC Solution

The PTC Product Development System (PDS) provides a single version of critical compliance data and documents, with comprehensive analytical tools to test and maintain compliance with FDA regulations. Furthermore, the PDS delivers critical content and process management capabilities that support demanding regulatory requirements, such as electronic records, electronic signatures, change tracking, auditing, and complex compliance documentation (See Fig. 2). Lastly, the PDS is an integral solution that scales to meet whatever regulatory challenges your company is facing–now and in the future.



Signature History Report

Signature History - Report

Doc Number	Version	Signature	Role	Event Date	Vote	Signature Info	Change Object	Object Type
0000000067	A	Ptc User1	ASSIGNEE	2005-01-20 11:59:31 EST	-	Examine the document and give your final approval. Then give your e-signature and complete the task.	-	-
0000000067	B	Ptc User1	ASSIGNEE	2005-01-20 12:34:19 EST	-	Examine the document and give your final approval. Then give your e-signature and complete the task.	-	-
0000000067	C	Ptc User1	ASSIGNEE	2005-01-30 16:47:31 EST	-	Examine the document and	-	-

Fig. 2. The Signature History Report, a feature in the Medical Device Template, serves as an electronic time-stamped audit trail which includes the printed name of the signer, the date and time the signature was executed, and the meaning (such as review, approval, etc.) associated with the signature.

Bear in mind that an automated and optimized regulatory compliance process not only requires superior technology, but it also requires companies to streamline their day-to-day processes. Just as important, companies need to ensure that everyone across the organization understands and adopts the new process and technology. With the PDS, you can rest assured that you are using an audited and validated system to automate your compliance. The PDS enables you to automate workflow, so you have complete visibility into every project, and you can quickly determine the status of a project or change. You can also ensure compliance by automating manual tasks, such as notification of new training when a change has taken place (See Fig. 3). Furthermore, the results of such training are automatically captured, as well. This, in turn, results in better audit performance.

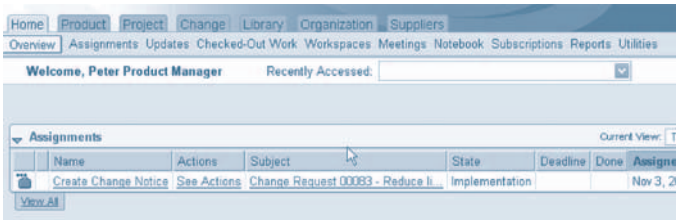


Fig. 3. Electronic task assignment and notification streamlines the review and approval processes.

Product quality and compliance are directly related: the better the quality of your product and records, the better your compliance. And both compliance and quality management affect all systems. The PDS is an integral system, ensuring that all your systems are drawing from a single source. This provides consistency and accuracy throughout the product lifecycle, as information is reused rather than recreated.

Critical Capabilities

In support of hardwiring compliance into your detailed design, the PDS can help you:

- Define business rules to automatically govern processes, and records management policies
- Manage compliance documentation in a central repository and under change control
- Create and manage compliance documents from multiple authors who use multiple authoring tools
  - Manage document change and lifecycle status in a controlled, collaborative environment
  - Conduct a full text search to easily locate and reuse compliance documentation
  - Integrate reference content from third-party sources
- Collect, track and approve process deliverables via collaborative project workspaces
- Streamline compliance document creation in multiple formats with dynamic publishing
- Incorporate hazardous material information into product documentation
- Define libraries that provide a central repository for requirements documents and provide revision history, library services, workflow and routing, document templates and change notification
- Create requirements documents as reusable components, assemble them into a single document, and publish in multiple formats
- Model the requirements process and enforce process consistency across product development projects with project execution and template reuse capabilities

- 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

PTC Medical Devices Template

The Medical Devices Template, along with Windchill® PDMLink®–PTC's industry leading data management product–is a solution that combines lessons learned and best practices from over 20 years of PTC experience helping medical device and equipment customers. The Medical Devices Template adds critical capabilities to Windchill PDMLink to support the security, traceability, and automation requirements established by FDA regulatory codes including 21 CFR Part 11.

Benefits

- Reduce the time needed to obtain regulatory approval
  - Generate compliance documents faster through electronic data management controls
  - Reduce change management cycle with automated support for corrective action reports (CAR) and corrective and preventative action (CAPA) processes, and authenticated electronic signatures
  - Improve efficiency by eliminating the need for paper-based processes
- Prove and enforce compliance with FDA regulations
  - Track FDA regulatory documents, including DHF and DMR
  - Ensure consistency with FDA-mandated controls and security features
  - Record compliance with change management processes
  - Ensure user compliance through recommended standard operating procedures
- Lower total cost of ownership
  - Apply out-of-the-box capabilities specific to the Medical Device Industry, eliminating the need for a custom solution
  - Save valuable setup time with initial configuration based on industry standards and best practices
- Quick, low-risk implementation
  - Fixed-price service engagement delivered by experienced consultants, minimizing risk
  - Proven methodology focuses on successful adoption of the solution
  - Two-week, packaged service ensures a quick return

Features

- Security
  - Full User Name identification
  - Read/Write or Read/Only document access control
- Auditing and document management
  - Signature manifestation includes electronic signatures, signature history and PDF rendering
  - Automatic creation and setup of DHF and DMR
  - Support for additional FDA-specific document types
  - Lifecycle synchronization module controls the promotion of lifecycle state for structured parts and documents
- Standard Operating Procedures
  - Incorporates PTC best practices and lessons learned from years of implementations
  - Includes access to consultants with many years of practical experience
  - Provides fully documented installation to ease future maintenance
  - Offers recommendations for future development to maximize the return on your investment

After 20 years of deploying process and technology improvements across thousands of customer sites, PTC has a worldwide Global Services team that understands what's required for companies to be successful. We offer solutions that include the right blend of process consulting, system implementation, and education services, so customers realize the most value from their Product Development System investment. We implement industry best practices that fully leverage PTC technology, so companies take advantage of its full potential while avoiding costly customizations. Plus, each of our solutions incorporates a unique training approach that accelerates the adoption of new technology and processes.

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, such as the PTC Product Development System and Medical Device Template, medical device manufacturers can hardwire compliance into their product development processes. 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.

Furthermore, 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 competitive market.