



Software Development for Medical Devices

OVERCOMING THE CHALLENGES OF COMPLIANCE, QUALITY AND COST

Software is fast becoming the differentiator for manufacturers of medical devices. The rewards of software innovation are balanced by the risks and challenges of regulation, stringent quality requirements, market pressures, and significant complexity. Balancing these competing interests requires tailored application lifecycle management tools that address the unique needs of medical devices companies.

Software can serve as a source of innovation and a key differentiator for medical devices, especially given the adaptability of software and the speed at which software changes can be prototyped and implemented. Software is also becoming more voluminous and complex, which creates significant risk.

To further complicate matters, software components used in medical devices fall under regulatory scrutiny. Two prominent regulatory bodies include the FDA for medical device products marketed in the U.S., and the European Medical Device Directive for medical device products marketed in the European Union.

Food and Drug Administration (FDA): 21 CFR Part 11 & Part 820

The U.S. Code of Federal Regulations (CFR), including 21 CFR Part 11, Electronic Records and Electronic Signatures and 21 CFR Part 820 Quality System (QS) Regulations (as well as ISO 13485 specifications) defines a number of practices and processes which must apply to the development of software that acts as a component of a medical device or is used to aid in the production or manufacturing of a device.

European Medical Device Directive (MDD): 93/42/EEC

The Medical Device Directive (MDD) is a harmonised European standard which protects against the risks associated with the design, manufacturing and packaging of medical devices. Compliance with the requirements of the Medical Devices Directive is declared by placing the CE marking on the product, and supplying the device with a Declaration of Conformity. Conformity requires a series of assessments and examinations of the quality system and examination of the product type and design dossier relating to the product.

In addition to market-specific regulatory requirements such as the FDA 21 CFR 820 and the European Union Medical Device Directive, ISO 13485 provides an overarching ISO standard for quality management systems;

Medical Devices Defined

“Any instrument, appliance, material..., including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of... diagnosis, prevention, monitoring, treatment or alleviation of disease...”

ISO 13485, Quality systems – Medical devices:
Particular requirements for the application of ISO 9001

Medical Device Software

- Software used as a component of a medical device
- Software that is a medical device
- Software used in the production of a device
- Software used to manufacture a device
- Software used in the implementation of the quality system

General Principles of Software Validation;
Final Guidance for Industry and FDA Staff, Jan 2002.

Likewise, ISO 14971 focuses on risk management systems. Implementing each of these ISO standards and attaining certification can help uncover greater global market opportunities and make it easier to satisfy the market-specific regulatory requirements.

Regulatory pressures and increasing complexity – coupled with the increasing globalization of the market – creates an environment in which quality, reliability and safety compete with the business needs to reduce time-to-market and increase product development efficiency.

This paper reviews some of the key challenges facing the medical device industry and examines the role that a comprehensive and coherent Global Software Development platform – which manages all assets and processes in software-containing product development – can play in meeting these challenges.

Top Software Challenges in the Medical Device Industry

Compliance

- Management of Documentation and Records
- Identification and Traceability
- Document Controls and Change Management
- Managing Risk and Reducing Recalls

Device and Software Quality

- Growing Volume of Software and Product Variants puts Quality at Risk
- Cost and Consequences of Recalls

Cycle Time and Cost

- Increasing Market Demand and Competition
- Coordination Across Groups (Internal and Suppliers)

Compliance

Challenge	Global Software Development Solution	Benefits
Management of Documentation and Records	<ul style="list-style-type: none"> • All documents can be stored and versioned with appropriate access controls • Automatically generates design history file DHF reports 	<ul style="list-style-type: none"> • Reduce effort to create DHF from weeks to minutes
Identification and Traceability	<ul style="list-style-type: none"> • Unique identification of each document and asset • Named trace relationships between all assets 	<ul style="list-style-type: none"> • Significant time savings
Document Controls and Change Management	<ul style="list-style-type: none"> • Automated workflow for effective process enforcement • Powerful change control automatically documents all allowed changes 	<ul style="list-style-type: none"> • Automated and enforced processes • Full change history without overhead
Managing Risk and Reducing Recalls	<ul style="list-style-type: none"> • Simplified electronic tracking of requirements, risks and mitigations with relationships and dependencies • Automatically compute Risk Priority Number (RPN) • Automated support for V-Model with named relationships between requirements, design, and software assets and their associated verification and validation assets 	<ul style="list-style-type: none"> • Reduced risk • Improve productivity while maintaining compliance and managing risk

Management of Documentation and Records

Key Challenge: Massive volume of documentation is difficult to manage and reduces team productivity.

Solution Summary: Consolidate storage of all documentation in a system that supports electronic signatures.

Throughout the product lifecycle, a significant amount of documentation and records is required by both manufacturer and regulator in order to demonstrate thorough design controls, document controls and audit history. In the design and development phase, regulatory requirements such as CFR 820 Subpart C titled “Design Controls” specifies that a “manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device...” the European Medical Device Directive provides similar guidance that “the application must describe the design, manufacture and performances of the product in question...” Further advice is also provided by both regulatory bodies on steps to be taken for reviewing, verifying and validating designs. The FDA specifies the retention of a design history file (DHF) to record all design change history, while the MDD specifies a similar technical file package to document testing data, risk analysis, requirements and cross-reference with any change documentation.

These detailed records, requirements specifications and design documents are commonly maintained through the use of Microsoft Office tools or some form of issue tracking tool, in order to prioritize and manage change records. This approach makes it difficult to keep all of this disparate data accurately synchronized. Collaboration by email or sharing documents on network drives is also inefficient, often resulting in inconsistencies or untimely communication.

To solve these challenges requires consolidation of key product documentation in one coherent Global Software Development platform, with change control over all assets. In addition, the platform that stores these documents and records needs to auditably capture asset history. Finally, the storage of electronic signatures on records or changes is often required by regulatory bodies (e.g., US Federal 21CFR Part 11).

Identification and Traceability

Key Challenge: Creating and maintaining trace relationships between records is arduous and time consuming.

Solution Summary: Simple, automated trace management and reporting.

In addition to the storage of documentation and records, the identification and traceability of relationships between those artifacts is also important. Traceability ensures that individual assets such as requirements, design specifications or software code can be traced through the entire product development lifecycle – including connection to any needed corrective or preventive action that might arise). Achieving this traceability can be overwhelming to manage manually even for a single medical device; it can result in traces across hundreds of documents. Managing these traces across disparate toolsets and repositories can require person-weeks of effort and can result in human error or omissions.

To minimize the overhead in this process, capturing all assets in a coherent Global Software Development platform permits automation that ensures that each document – as well as the individual elements of a document or software component – has a system-generated unique identifier. As users then decompose requirements into more detailed technical requirements, specifications and software components, they can establish trace relationships using these unique identifiers.

Automated trace reporting from within a single Global Software Development platform can also aid in the identification of missing traces and highlight areas of concern. This ability also means that traceability matrices from the product documentation set can be generated with mouse-clicks instead of taking weeks.

Document Controls and Change Management

Key Challenge: Cost-effective change management and capture of change history.

Solution Summary: One coherent platform with automated change control and workflow support.

With any product lifecycle, change is inevitable. In a highly regulated environment, it is critical that all aspects of change are documented and auditably captured. To effectively track changes, it is important to have a method of tracing the change to the specific affected requirement. This traceability is best served by requirements documented in a shared repository, with clear identifiers that distinguish between requirements.

A requirements change process can be similar to a coding change or defect tracking process. You first need to describe the change and the scope, and then the change needs to follow a defined process that involves review and authorization. Change records should be reviewed by a change review board or project team that has the necessary skills to evaluate the importance of the change and the cost or impact of implementing it.

As change is implemented, it is critical to auditably identify which change occurred, both within the documentation and within the software. A coherent Global Software Development platform addresses this need by providing process and workflow controls that support the recording, prioritization and review of change records, with complete traceability to the documentation and affected software artifacts. These change records can then be reported on and automatically included in history files and change reports to satisfy regulatory reporting requirements.

Managing Risk Exposure and Reducing Recalls

Key Challenge: Tracking risk with associated preventive and corrective actions is a large burden, especially if tracking is manual.

Solution Summary: Automated failure modes and effect analysis (FMEA) support integrated with change management.

Product defects are less expensive to fix if they're found early in the development process. In the medical devices market, product recalls can impact not only product profitability, but can also affect the overall corporate brand. To mitigate this risk, organizations must implement best practices that identify preventive measures and take corrective action. This need places an additional burden on traceability.

Preventive action is the practice of determining potential product faults and taking proactive measures to reduce the likelihood of occurrence. FMEA is one approach to implementing support for preventive action. FMEA provides an analytical approach to potential failure modes and their associated causes. When considering possible failures in a design – which can impact safety, cost, performance, quality and reliability – an engineer can get much information about how to alter the development/manufacturing process, to avoid these failures. FMEA provides an effective tool to determine which element presents the greatest risk based on priority or severity, and therefore which action is needed to prevent a problem before it arises. An adaptable data model is therefore required to be able to effectively capture these risks, prioritize them and trace them to their preventive or corrective action. The same model must contain evidence demonstrating that the risk has been mitigated.

Corrective action is required to respond to a variety of real-world events and conditions, including non-conformance, and audit issues, as well as customer- or patient-reported complaints. When a complaint or other issue is captured, it should automatically trigger an appropriate workflow to communicate that concern to reviewers who are responsible for taking further action. This capability needs to be tightly integrated with the change management process and is best addressed by managing all the assets and activities in a single Global Software Development platform.

Device and Software Quality

Challenge	Global Software Development Solution	Benefits
Growing Volume of Software and Product Variants puts Quality at Risk	<ul style="list-style-type: none"> Reuse of key engineering assets, including requirements, code and test cases Tracability links across projects and products to measure the true cost of defects and change requests 	<ul style="list-style-type: none"> Ability to perform impact analysis Measure the costs of defects and ensure resolution across the entire product line
Cost and Consequences of Recalls	<ul style="list-style-type: none"> Traceability to corrective action and preventive action Impact analysis capabilities to identify impact across the entire product line 	<ul style="list-style-type: none"> Minimize the recurrence of defects More quickly identify the overall impact and cost of compliance or adverse events

Growing Volume of Software and Product Variants Puts Quality at Risk

Key Challenge: Dealing with the complexity of software products and product lines.

Solution Summary: Reuse capabilities and traceability provide greater understanding of complex software products and the dependencies or impact of change across the product line, leading to better quality and less rework/error.

The introduction of more advanced medical device technology such as products with additional monitoring technology means that the volume of software as an overall component of medical devices is increasing. The introduction of software into the medical devices industry creates added complexity. Design documentation and change management practices are not limited to hardware components. The challenge with software is its inherent propensity to be reused. As reusable software modules or components are developed for so-called “utility functions,” the cost of tracking where that software is used increases. This reuse and increased complexity can be difficult to manage, if done so poorly, the quality and reliability of the software are jeopardized.

Software Product Lines and variant management become key concepts to support the complexity of multiproduct-line software development. The benefit to an organization in formally adopting a software product lines methodology is in the economies of scale, for the reuse of requirements, design specs and source code. However, these reuse practices also require sophisticated practices and processes for managing reuse and for dealing with software defects across the product lines. Change management and defect management processes need to support the categorization by product line for accurate measurement of the true cost of change and complaints.

Using a Global Software Development platform to manage software development and documentation for medical devices is the ideal path for companies that want to leverage the software product lines approach. Greater reuse and modularization of software lead to greater efficiency, shorter cycle times and more consistent software quality.

Cost and Consequences of Recalls

Key Challenge: Timely assessment of nonconformity to assess impact and resolution and to protect brand.

Solution Summary: Impact analysis capabilities are critical to identifying the overall impact of nonconformity, the true cost and scope of an issue, and the issues root cause.

How well a company manages regulatory non-conformity matters can have a significant effect on the future success of the product, the extent of the company’s liability (or financial loss) in the event of significant problems, and the value of a company’s brand and reputation.

To reach a recall decision, careful analysis and evaluation of adverse-event reports and identification of specific products or product lots are required. Impact analysis capabilities are essential to truly identify the revisions of software that may be affected by a defect and to understand the extent of that defect. Traceability is another key factor in being able to demonstrate

that the necessary Corrective and Preventive Action (CAPA) plan has been put in place and that the necessary root-cause analysis has been conducted.

A company’s success in interacting with regulators and communicating with health-care professionals, the media, and its own employees can have a major impact on future perceptions of the company as well as possible liability. It is also important to determine whether a device failure occurred and to identify and correct its cause in order to get that product back on the market after a recall, to recoup the product investment to date.

If all product documentation and software are stored in a comprehensive and coherent Global Software Development platform, not only is it less likely that nonconformity observations/citations will be issued (since regulatory reporting has been consistent and accurate), but the time and effort required to respond to nonconformity are drastically reduced. This translates into more rapid and more accurate responses, which can mitigate the potential risk and damage of nonconformity.

Cycle Time and Cost

Challenge	Global Software Development Solution	Benefits
Increasing Market Demand and Competition	<ul style="list-style-type: none"> • Process improvement • Streamlined process • Electronic signature and approvals process • Automated compliance reporting 	<ul style="list-style-type: none"> • Simplify areas of process; encourage lean and agile practices where appropriate • Automate compliance reporting as a byproduct of the process
Coordination Across Groups (Internal and Suppliers)	<ul style="list-style-type: none"> • Geographically distributed development and communication • Capability to import and export the data for seamless interchange • Process automation and enforcement 	<ul style="list-style-type: none"> • Improved internal communication • Improved external communication

Increasing Market Demand and Competition

Key Challenge: Launching innovative products and remaining competitive in a global market.

Solution Summary: Automation of processes to streamline the amount of time required to attain premarket approval and deliver product to market.

For medical device companies, there is a constant need to balance agility with compliance and quality. Larger companies can be at a competitive disadvantage as more of small niche players are introduced into the market. Innovation must be encouraged regardless of company size, but not at the cost of compliance and quality issues that could hinder brand credibility. Annual growth in the medical device industries is estimated at six percent annually with market demand rising.

Medical device companies are particularly interested in learning how to automate the internal approvals of premarket approval paperwork and ensure that regulatory submissions are timely and thorough enough to pass the stringent quality regulations in place. Management of software and documentation in a coherent Global Software Development platform means that internal processes will not bottleneck with these agencies – thereby preserving the time-to-market for new and updated medical device products. This is equally important for smaller organizations bringing their first device to market and larger firms with multiple product lines.

Coordination Across Groups (Internal and Suppliers)

Key Challenge: Leveraging a global network of resources and suppliers.

Solution Summary: Collaboration capabilities that provide realtime notification across disparate, geographically distributed teams and capabilities for importing/exporting data for suppliers.

Many parties are involved in the development, launch and maintenance of innovative medical device products. Large medical devices companies may structure themselves internally to take advantage of geographically distributed resources, maximizing the amount of development that occurs over a 24-hour period. Additionally, communication with suppliers is continuous to ensure supply chain dependencies are understood.

Support for geographically distributed teams must include effective communication and traceability across geographical and cultural boundaries. This ensures that common processes are followed and that traceability and compliance documentation can easily be generated regardless of who may be involved in the engineering process.

Communication with external suppliers should be simplified through emerging technology standards such as Requirements Interchange Format (RIF) to allow requirements documents and specifications to be seamlessly shared between suppliers and OEMs. Although these standards evolved out of the automotive industry, by adopting XML they made it possible for a diversity of product companies to produce documentation that is more easily shared – reducing turnaround times for change requests and defects.

Any solution deployed to manage requirements, documentation, source code and other assets across a distributed development organization must enable accurate and consistent collaboration among disparate stakeholders. The ideal solution is a Global Software Development platform that has the adaptability to address the functional and technology requirements of those disparate stakeholders, while seamlessly scaling across the enterprise.

Conclusion

Given that software represents the great opportunity for innovation and competitiveness as well as a great challenge in terms of risk, complexity and regulation, medical device organizations must take control of their software development with appropriate technology solutions.

The reality is that the complexity and rate of change for embedded software are rapidly outpacing the ability of organizations to address these issues with manual processes and disconnected point tools. The only way to mitigate risk while “priming” the organization for continuous innovation is through the consolidation of all software assets and activities into a single, unified solution. Only with such a solution will medical device organizations get the end-to-end traceability that is needed for success, while avoiding the problems, errors and delays that are generated by “best-of-breed” solutions.

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