Jama software®

The Complete Guide to ISO 13485 for Medical Device Development

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1 Introduction to ISO 13485

In the complex world of medical device development, teams not only face challenges of innovation, but also a shifting regulatory environment and evolving standards.

Balancing the competing interests of customers and stakeholders with the guidance and regulations from different entities across global boundaries presents challenges that even the most organized and methodical teams may struggle to meet.

In this environment, systems thinking can greatly improve the ability of medical device development teams to get products from the idea stage to market. By breaking down complex problems into manageable pieces, teams can better evaluate their systems and streamline and strengthen processes.

Using an applied systems approach will also help resolve inefficiencies in the development process and produce the outputs necessary for the design history file (DHF).

A growing number of organizations and teams are already pursuing a general systems approach by applying the guidance in ISO 13485:2016. This standard helps define a framework for the Quality Management System (QMS) for medical device development and pushes the development process naturally toward a systems approach. But for those teams that have not yet adopted the ISO 13485 standard, adding one more document or piece of guidance to the overall process can feel like another layer of complication.

It doesn't have to be. Adopting ISO 13485 can help standardize and systematize the medical device development process. Though it may look daunting at first, once adopted, ISO 13485 can streamline processes and position organizations for a better outcome with regulatory requirements.

This guide will untangle everything your medical device development team needs to know about ISO 13485.

Key Takeaways

- ISO 13485 and systems thinking go hand-in-hand; teams will find that adoption of ISO 13485 directs them toward systems thinking.

- Adoption of ISO 13485 will streamline processes and position medical device teams for better regulatory outcomes.

- ISO 13485 is a stand-alone document; however, it closely aligns with ISO 9001:2008.

- ISO 13485 and ISO 14971 are related, but ISO 14971 is more focused on risk management — the two standards can be used in tandem.

- ISO 13485 is not mandatory; teams can develop a Quality Management System (QMS) without the standard as long as it meets regulatory requirements. However, adoption of the ISO 13485 will create a QMS that is ideally positioned to meet the requirements of various regulatory and legislative entities, including the EU and US.

2 The Purpose of ISO 13485

The Purpose of ISO 13485

ISO 13485:2016 was developed by the International Organization for Standardization (ISO) to outline the standard for a Quality Management System (QMS) for the design and manufacture of medical devices.

The ISO defines "medical device" as "a product, such as an instrument, machine, implant or in vitro reagent, that is intended for use in the diagnosis, prevention and treatment of diseases or other medical conditions." ISO 13485 is a stand-alone document designed for use by organizations of any size involved in any stage of medical device development, from design to production to installation to service of devices. Both internal and external parties can use the standard to support the auditing process.

ISO 13485 is the most common standard for quality management in the field of medical device development across the globe. Adoption of the standard indicates a commitment to the highest quality and safety across the development process, and it provides a foundation for QMS requirements.

While not required by all government entities, ISO 13485 does provide a good foundation for addressing regulations such as the EU In-Vitro Diagnostics Regulation (IVDR).

FDA Final Ruling on QMSR

On January 31, 2024, the FDA issued a final rule amending the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) Regulation under 21 CFR 820 to align more closely with the international consensus standard for Quality Management Systems for medical devices used by many other regulatory authorities around the world.

This rule amends 21 CFR 820 by incorporating by reference the quality management system requirements of the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act)

3 Requirements for
ISO 13485 Adherence

Requirements for ISO 13485 Adherence

Though adoption of ISO 13485 may look complicated or daunting, in reality, adhering to the standard helps eliminate some of the ad-hoc nature of requirements and systems in the medical device field.

With increasing worldwide adoption of ISO 13485 by both companies and government entities, the medical device industry should start to realize some harmonization and consistency of processes and systems.

This standardization will help streamline the industry overall and allow important innovations a smoother and potentially faster route to market.

The requirements to obtain ISO 13485 certification start with a QMS. ASQ defines a Quality Management System as "*a formal system that documents the structure, processes, roles, responsibilities and procedures required to achieve effective quality management.*" The QMS must include documentation that defines the overall scope and implementation of the QMS; important documentation includes Quality Policy, Quality Objectives, and Quality Manual.

Bottom Line

These documents should be sure to address customer requirements. In addition, organizations need to create mandatory and additional processes and requirements necessary for all stages of development. Examples of documents required by ISO 13485:2016 can be found here.

ISO 13485 Version Guidance

The current version of ISO 13485 is **ISO 13485:2016**, published in March of 2016. Additional regulatory or standards guidance that aligns with ISO 13485:2016 includes **ISO 9001:2008 (not 2015)** and **AAMI TIR102:2019.**

Why Startup Medical Device Companies Should Prioritize Requirements and Risk Management Before QMS

For startup medical device companies, prioritizing requirements and risk management over an electronic quality management system (eQMS) is crucial. Early investment in design controls and risk management ensures compliance and better product outcomes from the start, unlike an eQMS, which may not be necessary until later in product development. Managing complex requirements and risks early on streamlines regulatory processes, while a simpler, staged approach to quality management can suffice in the early years. This strategy optimizes resources and accelerates development.

Read the full article here »
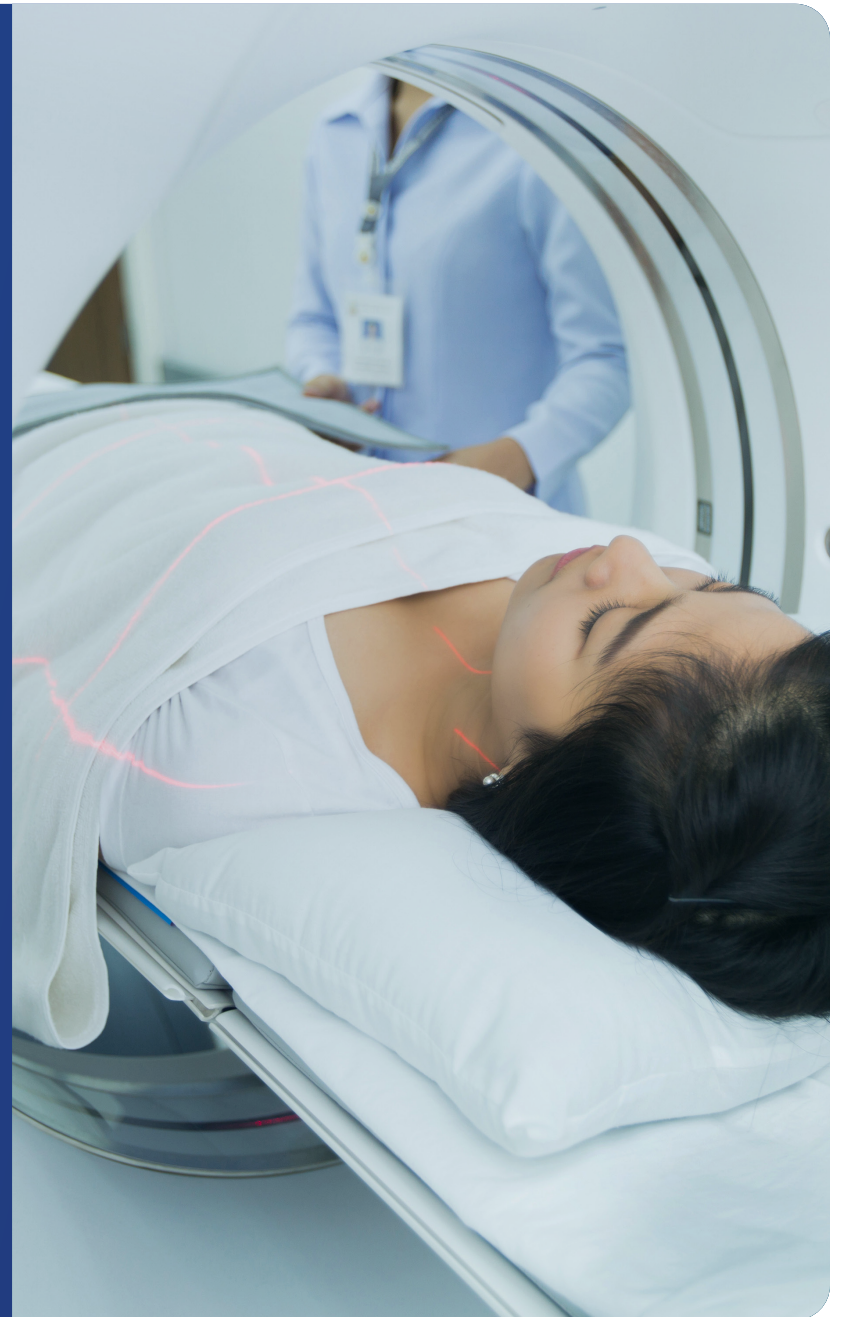
4 **The Difference Between ISO 13485 and Other Medical Device Standards**

The Difference Between ISO 13485 and Other Medical Device Standards

EN ISO 13485

The difference between the two standards lies in the inclusion of several tables in EN ISO 13485 that can help teams meet the requirements of three European directives for medical devices (EU directives 90/385/EEC, 93/42/EEC, and 98/79/EC). The tables in EN ISO 13485 align the requirements of ISO 13485 with these European directives, allowing teams to see how adoption of the standard will help meet the requirements of the directives.

Pro Tip

It's important to note that the European Union Medical Device Regulation (EU MDR), released in 2017, supersedes the previous EU directives.

A future release of EN ISO 13485 is expected to show alignment with the EU MDR.

Learn More >>

ISO 9001

ISO 13485 is based on ISO 9001:2008, which is an internationally recognized standard for QMS in any organization or industry. However, ISO 13485 goes beyond the ISO 9001 standard to address the specific needs of the medical device industry. Additional requirements for the medical device industry include:

- Specific documentation requirements for medical device files

- Work environment and contamination control requirements

- Production requirements that address cleanliness of products and assurance of a sterile environment where appropriate

- Regulatory reporting guidance

ISO 14971: ISO 14971 and ISO 13485 are related, but ISO 14971 includes greater detail regarding risk management requirements.

The two standards work together to create a QMS that addresses the full spectrum of requirements unique to the medical device industry.

Pro Tip

It's important to recognize that ISO 13485 aligns with the 2008 version of ISO 9001 — not the 2015 version. The ISO 9001:2015 includes requirements that were not deemed relevant to the medical device industry, so the ISO 9001:2008 remains the standard most closely aligned with ISO 13485.

ISO 14971

ISO 14971 and ISO 13485 are related, but ISO 14971 includes greater detail regarding risk management requirements. The two standards work together to create a QMS that addresses the full spectrum of requirements unique to the medical device industry.

WHITEPAPER

To learn more about ISO 14971, download
Application of Risk Analysis Techniques to Satisfy ISO 14971.

In this whitepaper, we cover the main clauses of ISO 14971 — the FDA's mandatory standard for risk assessment in medical devices — and share how Jama Connect gives you a comprehensive way to manage risk and requirements throughout development.

In the world of medical device development, risk management carries higher stakes than many other industries.

Organizations and teams focused on mitigating risk and meeting regulatory requirements can find it cumbersome and time-consuming to manage requirements, especially with complex projects, and rigid systems which often require extreme effort for even the minimum requirement approval cycle.

Failure Mode and Effects Analysis (FMEA) is a risk management method that helps gather knowledge and preserve it for future development cycles. ISO 14971 provides a framework for identifying, controlling, and monitoring risks to ensure the safety of medical devices. ISO 13485 provides the framework to measure and monitor processes. Using both standards in tandem, medical device development teams can meet regulatory requirements for both the QMS and risk management.

CASE STUDY
See how Jama Software® helped microsurgical robotics company, Microsure, ease the path to compliance and speed time to market.

Read the full story »

5 **Steps for Successful ISO 13485 Adoption**

Steps for Successful ISO 13485 Adoption

The first step toward certification to the ISO 13485 standard is adoption. For organizations just starting the process of adoption and certification, the following steps can serve as a general guide.

STEP 1

Management Support

Pursuing an initiative such as adoption of ISO 13485 is far more likely to succeed if management supports the endeavor. If the adoption is not driven from the top down, pointing out the advantages of ISO 13485 can help gain management buy-in. Secure support from the top for training and audit expenses.

STEP 2

Training

Identify key team members to pursue training in the standard. There are many documents and training courses available online; sites such as 13485Store.com.

STEP 3

Gap Analysis

Given the regulatory environment around medical device development, organizations that have not yet adopted ISO 13485 have likely already developed systems and processes to meet requirements for device approval. Align those systems and processes with the requirements of ISO 13485. The gaps that remain are the ones to address.

STEP 4

Development and Documentation

This step is likely the biggest phase of adoption of ISO 13485. In this step, those team members spearheading the adoption initiative will design and document all of the processes to meet the requirements of the standard. Once those processes are developed or modified, the team needs to document everything for the QMS.

STEP 5

Use the QMS

When all the systems are documented and in place, the team should actively use it for at least a few months before applying for audits or certification. Actively using the QMS will help identify additional gaps or insufficiencies in the QMS. When those challenges arise, the team can address them immediately and make adjustments as necessary.

Once the QMS is running smoothly internally, it's time to pursue certification.

Jama Connect Features in Five: Using Jama Connect with a Quality Management System (QMS) for Medical Device & Life Sciences

Learn how you can supercharge your systems development process! In this blog series, we're pulling back the curtains to give you a look at a few of Jama Connect's powerful features... in under five minutes.

In this short video, we:

- Provide insight on how Jama Connect is commonly used in the context of a medical device quality management system (QMS)

- Demonstrate key features that provide value to those responsible for quality and regulatory matters

- Offer clear guidance on how Jama Connect – a requirements management solution – supplements a separate quality management system within a cohesive ecosystem of complimentary applications

Watch the video »

6 ISO 13485 Certification

ISO 13485 Certification

If an organization is already certified to ISO 9001:2008 and can meet additional medical device requirements, the organization should be able to achieve certification to ISO 13485.

As of December 2024, certification to ISO 13485 is not mandatory. However, since ISO 13485 is the main QMS standard for medical devices globally, it may make sense to pursue certification even where it is not required. In addition, many organizations can find the standard beneficial even without pursuing full certification. Organizations that complete the certification will be able to demonstrate to regulators full comprehension of the standard as a result of certification. Finally, as the industry continues to move toward greater adoption of ISO 13485, and as government entities recognize the value of the standard in helping to meet regulatory requirements, it is possible that the standard will become mandatory.

It is important to recognize who and what is "certified" to the ISO 13485 standard.

- Only an organization can pursue certification to the ISO 13485 standard; people and devices cannot be ISO 13485 certified.

- A person can become an ISO 13485 Certified Lead Auditor upon completion of a 5-day training course. This auditor certification allows an individual to audit other companies.

- Organizations do not "join" ISO 13485 as it is not a membership group.

- There is no minimum or limit to the size of an organization that can be certified. Any organization, whether one person or one million people, can be certified.

To pursue certification, a company must:

- Follow the steps to implement an ISO 13485 quality management system.

- Contact a Certification Body or Registrar to request an audit of company performance against the ISO 13485 standard.

- Re-certify every three years to maintain current status.

7 **The Value Proposition of an Itemized Database**

The Value Proposition of an Itemized Database

Central to this transition is understanding the inherent value of itemized databases like Jama Connect. This section explores the tangible benefits, including real-time traceability, proactive change management, and improved product quality.

By embracing itemized databases, organizations can:

- **Accelerate Product Development Cycles:** By accelerating product development cycles, organizations can increase their market competitiveness and improve their ability to meet customer demands, while minimizing the risk of delays or missed opportunities caused by manual documentation processes.

- **Maintain Proactive Traceability:** By maintaining proactive traceability, organizations can demonstrate compliance with regulatory requirements, ensuring transparency and accountability throughout the development process, while enabling faster detection and resolution of issues before they escalate.

- **Gain Visibility into Progress and Coverage:** By gaining visibility into progress and coverage, organizations can identify gaps and redundancies
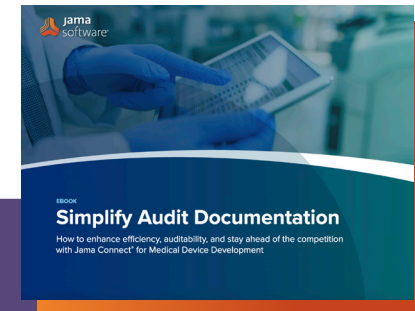
EBOOK

Simplify Audit Documentation by Leveraging the Power of an Itemized Database

In medical device development, reliance on traditional documents or legacy document-driven systems like Cognition Cockpit and Polarian poses challenges for professionals, particularly those in roles such as quality assurance.

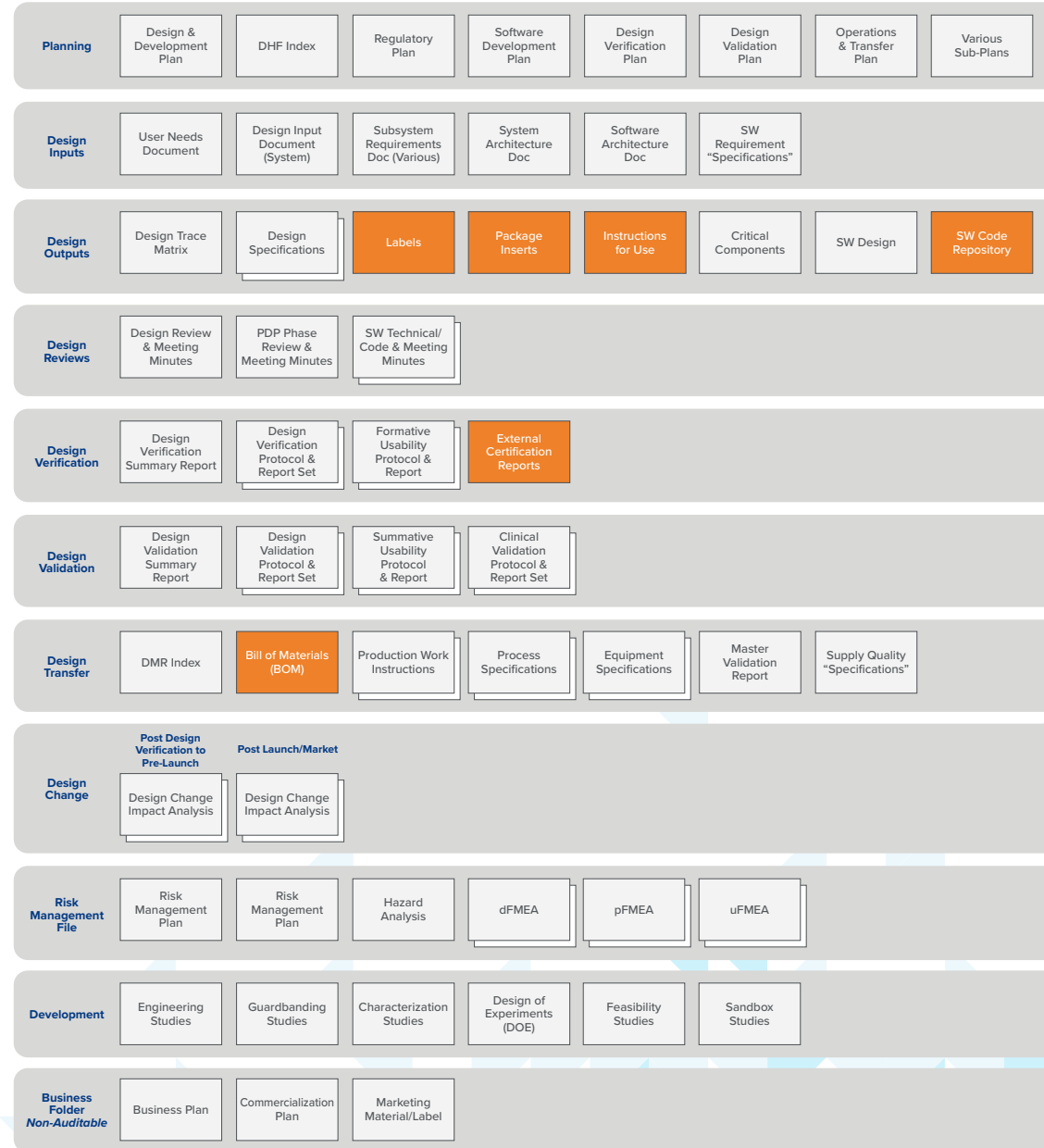Learn a better alternative in this ebook »

- in their documentation, prioritize requirements, and allocate resources effectively, improving overall product quality, and reducing the risk of compliance issues.

- **Proactively Manage Risks:** By proactively managing risks, organizations can reduce the likelihood of errors and minimize the potential impact of issues, ensuring patient safety and reducing the risk of product recalls, legal liability, or damage to reputation.

- **Link Suspect Items and Manage Change:** By linking suspect items and effectively managing change, organizations can streamline the change management process, minimizing the impact of revisions on other items, and ensuring that each change is properly reviewed and validated before implementation.

- **Maintain an Agile Workflow:** By easily maintaining an Agile workflow, organizations can support their development teams, empowering them to collaborate and innovate effectively, while ensuring that their processes remain compliant and traceable throughout the development lifecycle.

- **Enhance Documentation:** By enhancing compliance documentation, organizations can improve their ability to adhere to regulatory requirements and expectations, minimize the risk of non-compliance, and demonstrate their commitment to patient safety and quality outcomes.

- **Reuse Requirements:** By reusing requirements and enabling release management, organizations can optimize their resources, reduce duplicative efforts, and improve their ability to deliver products that meet customer needs and expectations.

- **Automate Version Control:** By automating version control, organizations can minimize the risk of errors caused by manual processes, streamline the review and approval of documentation, and improve their ability to manage multiple iterations and revisions while maintaining an accurate audit trail.

Integrating Itemized Databases with Document-Based Auditable Records

While itemized databases offer numerous advantages, the need to generate auditable documentation remains crucial. This section outlines a seamless workflow for integrating itemized databases with document-based auditable records. Leveraging Jama Connect's capabilities, teams can generate regulatory-compliant documents while maintaining traceability and version control.

Project Design History File (DHF) in System of Record

□ Support by Jama   ■ TBD Support by Jama

Category							
Planning	Design & Development Plan	DHF Index	Regulatory Plan	Software Development Plan	Design Verification Plan	Design Validation Plan	Operations & Transfer Plan	Various Sub-Plans
Design Inputs	User Needs Document	Design Input Document (System)	Subsystem Requirements Doc (Various)	System Architecture Doc	Software Architecture Doc	SW Requirement "Specifications"	
Design Outputs	Design Trace Matrix	Design Specifications	Labels	Package Inserts	Instructions for Use	Critical Components	SW Design	SW Code Repository
Design Reviews	Design Review & Meeting Minutes	PDP Phase Review & Meeting Minutes	SW Technical/ Code & Meeting Minutes				
Design Verification	Design Verification Summary Report	Design Verification Protocol & Report Set	Formative Usability Protocol & Report	External Certification Reports			
Design Validation	Design Validation Summary Report	Design Validation Protocol & Report Set	Summative Usability Protocol & Report	Clinical Validation Protocol & Report Set			
Design Transfer	DMR Index	Bill of Materials (BOM)	Production Work Instructions	Process Specifications	Equipment Specifications	Master Validation Report	Supply Quality "Specifications"
Design Change	*Post Design Verification to Pre-Launch* Design Change Impact Analysis	*Post Launch/Market* Design Change Impact Analysis					
Risk Management File	Risk Management Plan	Risk Management Plan	Hazard Analysis	dFMEA	pFMEA	uFMEA	
Development	Engineering Studies	Guardbanding Studies	Characterization Studies	Design of Experiments (DOE)	Feasibility Studies	Sandbox Studies	
Business Folder *Non-Auditable*	Business Plan	Commercialization Plan	Marketing Material/Label				

8

The Challenge of Document-Centric Workflows

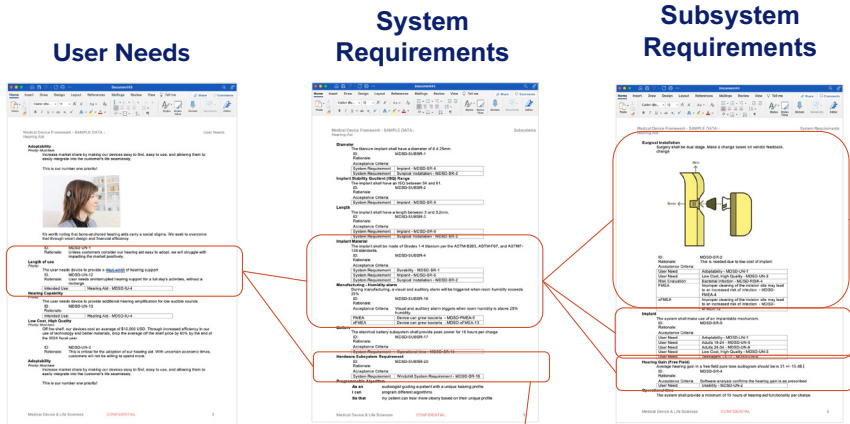# The Challenge of Document-Centric Workflows

Traditional product development processes for medical device companies revolve around document-centric workflows. This section highlights the inherent limitations and complexities associated with managing requirements, traceability, and change control solely through documents.
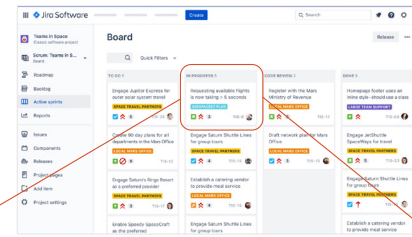
Challenges include:

- Manual traceability matrices often lead to a time-consuming and error-prone process, making it challenging to maintain accurate and up-to-date links between requirements, design elements, and test cases, which are critical for regulatory compliance and product quality.

- Version control issues can result in confusion, inconsistencies, and potential compliance risks, as stakeholders struggle to identify the most current documentation amidst multiple iterations, revisions, and parallel development efforts.

- Difficulties working in an Agile workflow can hinder traceability and documentation, as the rapid pace of iterations and evolving requirements make it challenging to maintain clear and auditable links between user stories, tasks, and regulatory documentation, impacting the ability to demonstrate compliance and validation.

Traceability is Managed Manually and Reactively

User Stories

User Needs

System Requirements

Subsystem Requirements

Test Protocol

Risk Evaluation

Requirements Traceability Matrix

Test Cases

- The absence of a single source of truth contributes to inefficiencies, as disparate document repositories result in data silos, inconsistent information, and difficulty in reconciling different versions of documentation, leading to confusion and potential errors in audits or reviews.

- Slow quality management processes can delay the verification and validation of documentation, impacting the timely detection and resolution of compliance issues, and the ability to demonstrate adherence to regulatory standards, potentially delaying product approvals and market entry.

- The risk of errors escalating during iterative design phases grows as manual documentation processes and fragmented tools make it difficult to track and manage changes, increasing the likelihood of overlooked requirements, design inconsistencies, and compliance gaps that can surface during regulatory assessments and audits.

>1,000X

110X

40X

16X

| Definition | Development | Integration Testing | System Testing | Acceptance Testing | Commercialization & Post Launch |

■ Faults Introduced ■ Faults Found ■ Cost to Correct

Source: INCOSE, NIST, Report
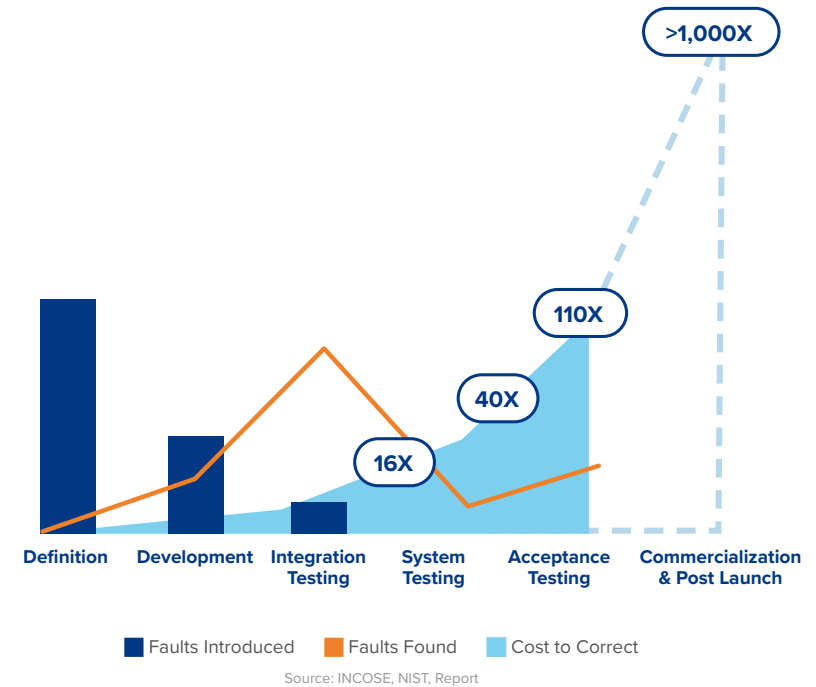
The Strategic Transition: From Word and Excel to Modern Requirements Management

Whether it's Microsoft Word, Excel, or a combination of both, trying to wrangle your product's requirements solely in documents carries a lot of risk and will gradually eat away at your company's bottom line. When you need precision, context, and accountability for your requirements, a modern requirements management solution is really the only answer.

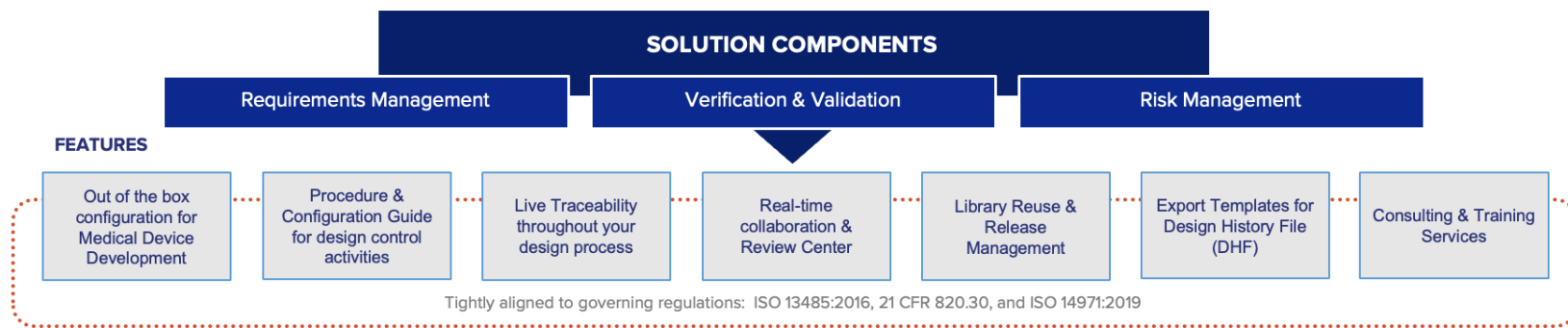**Read this eBook to learn more >>**

9 How Can Jama Connect Help?

How Can Jama Connect Help?

Beyond the initial product development phase, sustaining engineering requires ongoing maintenance and iterative improvements. This section discusses how itemized databases facilitate sustaining engineering efforts by enabling efficient change management, reuse of data, and seamless collaboration between teams. Jama Connect's integration with quality management systems ensures compliance with regulatory requirements while optimizing product lifecycle management.

Jama Connect's out-of-the-box Medical Device Framework is compliant with 13485 with available documentation consistent with regulation best practices.

SOLUTION COMPONENTS

| Requirements Management | Verification & Validation | Risk Management |

FEATURES

| Out of the box configuration for Medical Device Development | Procedure & Configuration Guide for design control activities | Live Traceability throughout your design process | Real-time collaboration & Review Center | Library Reuse & Release Management | Export Templates for Design History File (DHF) | Consulting & Training Services |

Tightly aligned to governing regulations: ISO 13485:2016, 21 CFR 820.30, and ISO 14971:2019

The Jama Connect Medical Device Framework includes:

- Configured Item Types, Pick Lists, and Views
- Relationship Rule aligned to Trace Matrix needs
- Workflows guiding requirement acceptance

- Project template
- Export templates for in-scope Design History File artifacts

With Jama Connect, teams can:

See what happens when there is a change and update living documents such as risk files and trace matrices

- Assess impact and suspect links
- Review documents for quality and consistency
- Re-baseline for document export

- Report on baseline comparisons
- Align engineering seamlessly with QMS

The Review Center in Jama Connect allows engineers, quality team members, and other stakeholders to asynchronously collaborate on requirements in Jama Connect and create actionable requests that automatically capture the history of changes (through review versions and baselines).

Jama Connect can also seamlessly integrate with tools across the development process and acts as a central hub of information — and provides integration solutions with market-leading tools for design and simulation, task management, lifecycle management, quality assurance, and testing. Teams can work in their preferred tools while ensuring all requirements are verified and validated to achieve complete traceability.
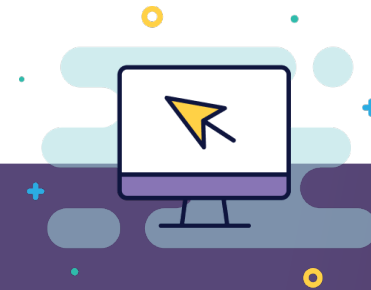
Leverage Jama Software's Procedure and Configuration Guide to Accelerate Alignment to Processes and Regulations

- Identify and align relevant parts of ISO 13485:2016, ISO 14971:2019 and 21 CFR 820.30 with recommended Jama Connect Procedures
- Gain specific instructions for the recommended use of Jama Connect to meet Design Control requirements from industry experts

10 **Conclusion**

Conclusion

Adopting the ISO 13485 standard is not an insignificant amount of work, but the payoffs are worth the effort. Teams that pursue adoption and certification will:

- Naturally move toward systems thinking in the development process

- Streamline systems and processes in a way that helps move devices to market more smoothly

- Align themselves with the bulk of the medical device industry as more and more organizations adopt the standard

- Position themselves for smoother regulatory processes and outcomes.

Of course, having the right tools at hand can help improve the ISO 13485 adoption and certification process. That's why teams depend on Jama Connect for Medical Device Development to make the journey from design to market as smooth as possible.

LEARN MORE
Jama Connect for Medical Device requirements management is purpose-built to reduce the effort required to achieve regulatory compliance by managing design controls for device requirements and related risks, simplifying regulatory submissions and audit preparations, and accelerating time to market.

Download the datasheet to learn more >>

Jama software®

Jama Software® is focused on maximizing innovation success in multidisciplinary engineering organizations. Numerous firsts for humanity in fields such as fuel cells, electrification, space, software-defined vehicles, surgical robotics, and more all rely on Jama Connect® requirements management software to minimize the risk of defects, rework, cost overruns, and recalls. Using Jama Connect, engineering organizations can now intelligently manage the development process by leveraging Live Traceability™ across best-of-breed tools to measurably improve outcomes. Our rapidly growing customer base spans the automotive, medical device, life sciences, semiconductor, aerospace & defense, industrial manufacturing, consumer electronics, financial services, and insurance industries. To learn more, visit us at jamasoftware.com.