Jama software®

WHITEPAPER

# Application of Risk Analysis Techniques in Jama Connect® to Satisfy ISO 14971

## How Medical Technology Companies Can Better Manage Risk and Speed Time to Market

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# Introduction

Medical product developers face tremendous pressure to bring innovative products that are safe and effective to market without delay. As the pace of innovation increases, medical devices incorporating both hardware and software components have become standard, and tech companies are taking note of the market opportunity.

Innovation also introduces new challenges for companies trying to outclass competitors and revolutionize patient care. Software issues in medical devices can be devastating, and failure to ensure that products are safe and compliant can result in patient harm, enormous fines, FDA recall, and brand erosion.

For instance, the second quarter of 2022 posted the highest number of recalls than the same quarter in any of the last five years. Additionally, software issues accounted for the second highest number of recalls.[1]

Given the stakes, safety, compliance, and speed are central concerns for medical device developers. And that's why tools and solutions that define requirements, mitigate risk, guide compliance, avoid errors, and streamline the development process are such valuable resources.

[1] Medtech Dive, August 2022

# FMEA vs. ISO 14971

In our experience working with over 200 medical product developers — whether they are established thought leaders, disruptive new players or both — we've recognized the importance of creating best practices for risk management that a diverse array of developers can leverage for success, rather than organization-specific approaches with limited transferability.

Medical product developers take different approaches to risk management, depending on their product and market conditions. Companies involved in developing medical products understand the importance of risk management, but their approaches can vary significantly in terms of the time it takes to manage risk, the ability to connect risks to specific requirements and tests, and the capacity to pull together relevant documentation for an audit.

To meet these challenges, medical product developers need a comprehensive approach to risk management.

**Organization-focused approaches is where Jama Professional Services comes in:** providing our customers with expert assistance in optimizing and influencing the platform, as well as industry-specific consultation and training. **To learn more, visit us here.**

Developed in the 1950s, failure modes and effects analysis (FMEA) is the first formal standard for risk management. FMEA is a bottom-up approach for identifying functionality and risk. It's a strong tool for assessing single-fault failure modes and reliability. In simple terms, FMEA determines whether the product works or not.

However, FMEA isn't necessarily sufficient to address the complexity of medical device development, and it's not the best tool for managing risk across the entire product lifecycle. Medical device developers must identify, assess, and evaluate risks for hazardous situations by considering every foreseeable sequence of events, including non-failure modes.

Restricting your risk management process to failure modes can overlook critical considerations, like patient safety, for medical device developers. Especially once a device has moved from development to production, risk analysis documentation and FMEA tends to be neglected and not kept updated.

Finally, the bottom-up FMEA process begins with features and explores the ways the features can fail, leading to harm. This necessitates that the object of the FMEA be at least partially designed before the analysis can begin. On the other hand, ISO 14971's top-down risk assessment begins with the sources of harm, which are identified based on the intended use, foreseeable misuse, and characteristics for safety. This means that the ISO 14971 process can begin sooner to guide the design from an earlier stage, reducing rework from the late discovery of risks, and improving overall quality and product safety.

## ISO 14971

The FDA requires risk assessment as part of design validation and prescribes ISO 14971 as the mandatory standard.

A nine-part standard that establishes a framework for risk analysis, evaluation, control, and management, ISO 14971 sees risk management as a product lifecycle process that encompasses development, production, and post-production.

ISO 14971 is a top-down analysis that builds toward a holistic goal: optimizing the health, safety, and success of the patient or end-user by understanding what type of harm might befall them.

Excel and other tools for document-based requirements management work for smaller projects, but spreadsheets don't scale to meet the needs of global teams working on large development projects. Excel simply isn't robust enough to account for the complexity and risk inherent to medical device development, and it can't provide the end-to-end traceability necessary for satisfying ISO 14971.

# Risks vs. Requirements

Jama Connect gives developers and stakeholders the structured, intuitive information system they need to enable collaboration and traceability within the risk management process.

By capturing risks and requirements in one tool, Jama Connect streamlines development and helps prepare your organization for regulatory audits.

Risk management is an inextricable part of the medical device development process. For medical device developers, risks are requirements. Risks may take different forms than requirements, and may be more scenario-based, but they are a core principle of product development and should be tied together in one powerful platform.

Analyzing risk helps teams track data and make decisions, which makes risk a natural fit for Jama Connect. Without risks integrated directly into Jama Connect, it's hard to make the case for complete traceability in your product development process, regardless of your industry or level of regulation.


**Want to learn more about understanding risk management for medical device development?**

In this on-demand webinar, industry and solution experts will explore how teams can integrate risk-based thinking into their product development lifecycle, including:

- Risk management in the medical device industry
- Guidance and best practices to follow
- How to manage risk analysis
- The importance of risk traceability throughout project activities

WATCH NOW

SECTION 1

# Meeting Challenges for Medical Device Developers

By looking at three common challenges faced by medical device companies, let's explore how Jama Connect helps teams manage risk simply and effectively during their development processes.

CHALLENGE **NO.1**

# Traceability in Risk Management

Many medical device companies continue to depend on Excel to capture risk data.

Connecting that information back to design controls is a cumbersome and error-prone process.

Excel doesn't allow for automated traceability, so risks and requirements don't live in the same system. This makes it tedious and time-consuming to conclusively demonstrate compliance with ISO 14971.

Without risk analysis integrated into Jama Connect, requirements and tests will be orphaned from risk and hazard analysis.

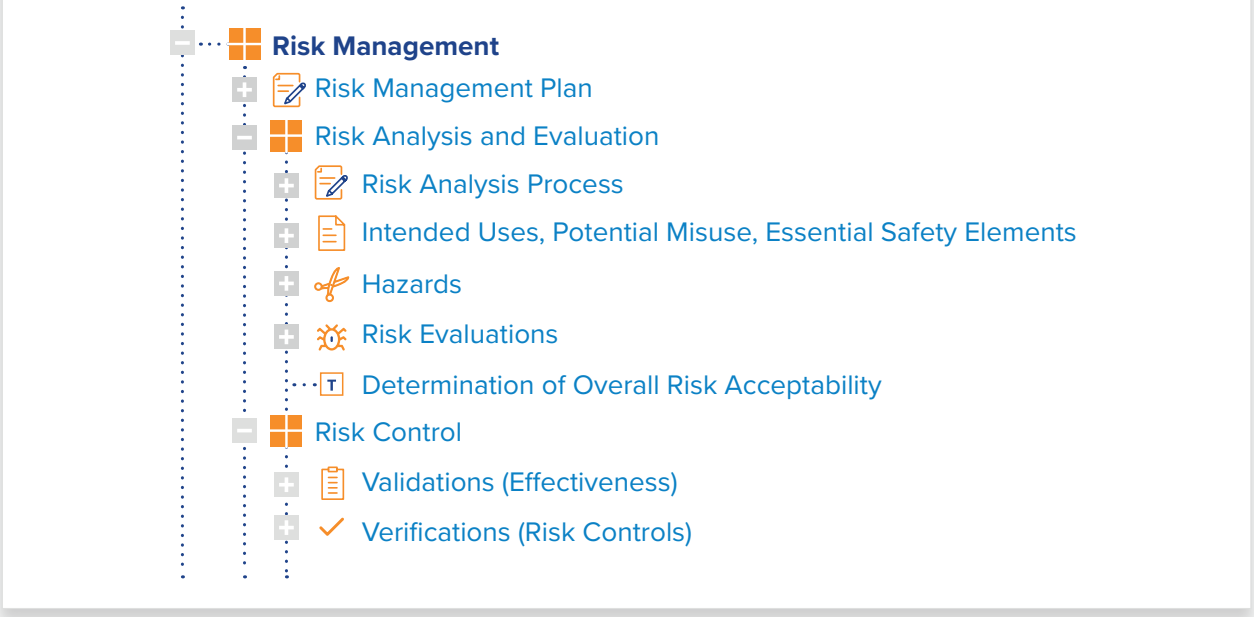
Jama Connect allows teams to easily connect risks, requirements, and testing in one system where requirements and test results stay live in real time.

The #1 problem product engineering organizations face is complying with traceability requirements spanning siloed teams and tools. Jama Connect Interchange™ is purpose-built to deliver Live Traceability™ across best-of-breed tools, including Microsoft Excel.

CLICK HERE to learn how Jama Connect's unique traceability model with continuous sync delivers Live Traceability.

CHALLENGE **NO.2**

# Templates




Jama Connect's out-of-the-box ISO 14971 framework provides industry-specific guidance to get you up and running much faster than a blank Excel spreadsheet. By using a guided template, you'll spend less time on setup and more time on what's important: identifying and managing risk.

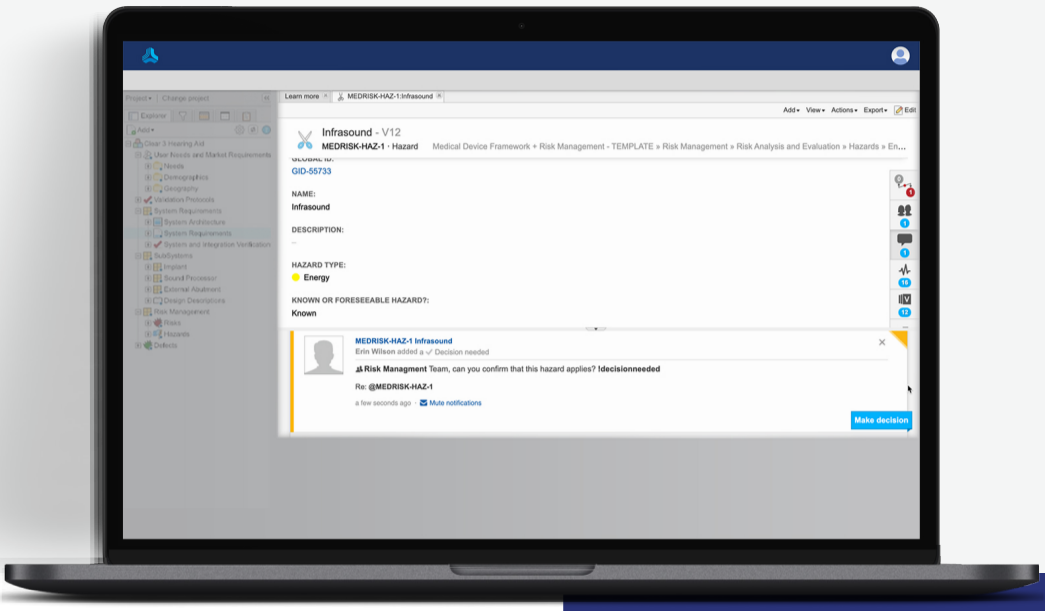
In Jama Connect you can create, modify and lock templates for product- or class-specific use to help ensure standardization across your organization.

Additionally, Jama Connect allows you to set values for probability and severity, and it also supports setting organization-specific risk levels.

To be successful, ISO 14971 requires that management provides evidence of commitment to its risk management process by making sufficient resources available to qualified personnel. Implementing and using Jama Connect's framework serves as a clear sign of commitment and is an excellent first step to successfully managing risk.

CHALLENGE **NO.3**

# Collaboration




Jama Connect makes collaboration easier and more powerful. You can share ideas by collaborating in real time and context is captured as you go, giving you a better understanding of the latest version.

ISO 14971 points out that evaluation of risk may include the judgment of a multi-disciplinary group of subject-matter experts. In today's world, this often means large teams with wide distances and time zones between them are collaborating on the risk management process. No tool facilitates the involvement and input of cross-functional experts as well as Jama Connect.

**Structured collaboration is the key to helping engineering teams streamline and optimize their product development processes.**

**Read this eBook to learn:**

- What structured collaboration is and how it can transform your product development process
- How structured collaboration enables innovation, cross-team alignment, and expedites the delivery of quality products
- The added business value of implementing structured collaboration in the requirements management process

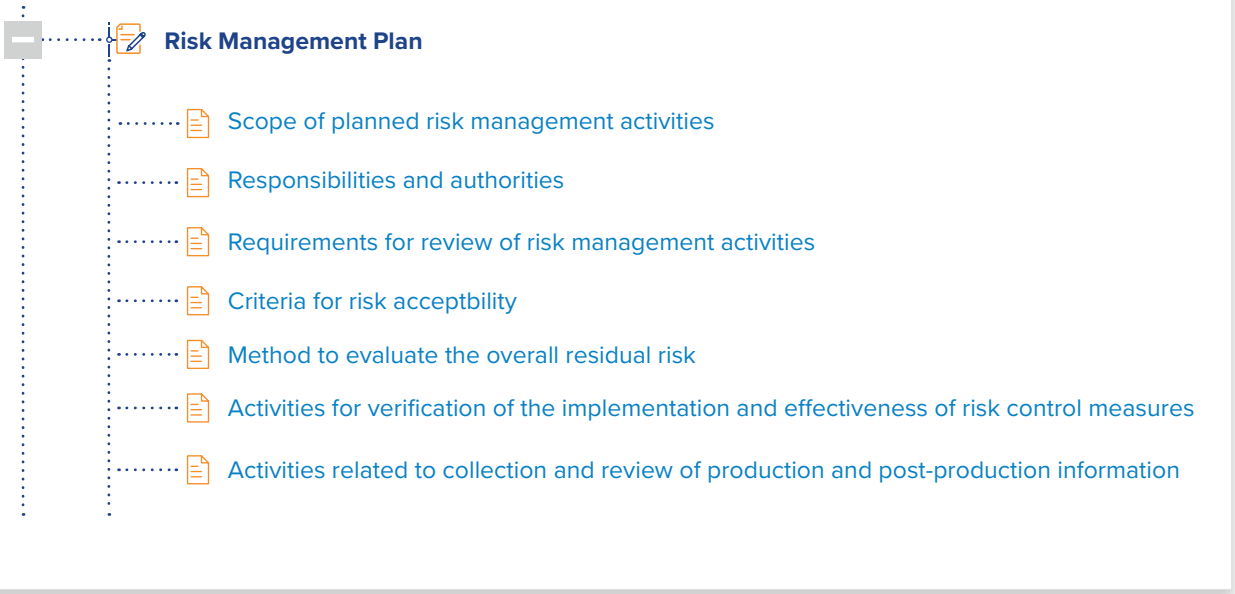
READ IT HERE

SECTION 2

# Jama Connect and ISO 14971

Now that we've covered how Jama Connect helps users address three common challenges in risk management, let's dig into how the Jama Connect provides guidance for teams using ISO 14971 to evaluate risk.

# Risk Management Plan




Clause 4 of ISO 14971 concerns how risk is organized and administered for your product line. It requires the formation of a Risk Management Plan throughout the development lifecycle.

The Risk Management Plan is the record of a planned process for risk management: who does what and when, how risks are scored, etc. It's a component of the Risk Management File, which contains all the outputs for risk.

Jama Connect guides compliance with Clauses 5, 6, 7, 8, and 10, which focus on how risk should be managed within the Risk Management Plan.

CLAUSE 5

# Risk Analysis

Clause 5 of ISO 14971 requires that medical device developers identify potential hazards and hazardous situations. Each situation and its potential consequences must be evaluated.

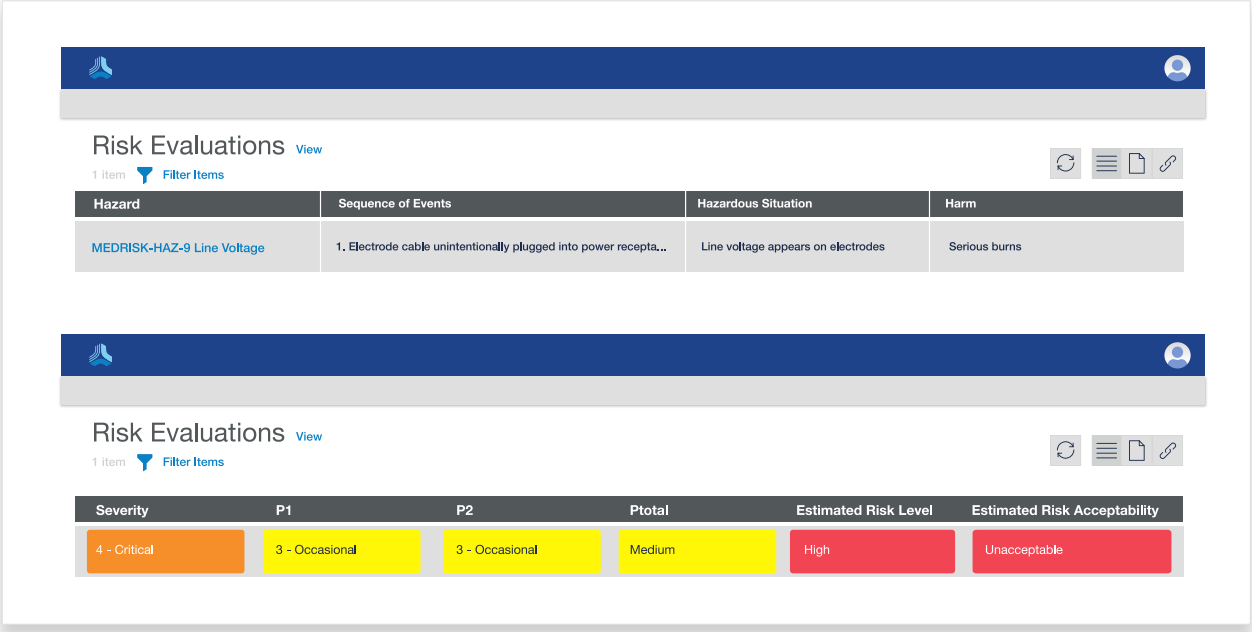
Jama Connect helps teams satisfy Clause 5 by defining a framework for capturing device-specific hazards, harm probability, and harm severity, ensuring no part of the traceability is overlooked or lost.

Jama Connect offers risk management item templates that require the capture of important information about the risk analysis process, including a description of the device, intended use and the scope of the analysis.

Teams can identify and evaluate potential hazards, sequences of events, hazardous situations, and harms in a single item type.

CLAUSE 6

# Risk Evaluation




Clause 6 requires evaluation of risk to determine acceptability for each hazardous situation. To satisfy Clause 6, teams take the overall risk level output from Clause 5 and determine whether the risk is acceptable according to the criteria defined in the risk management plan.

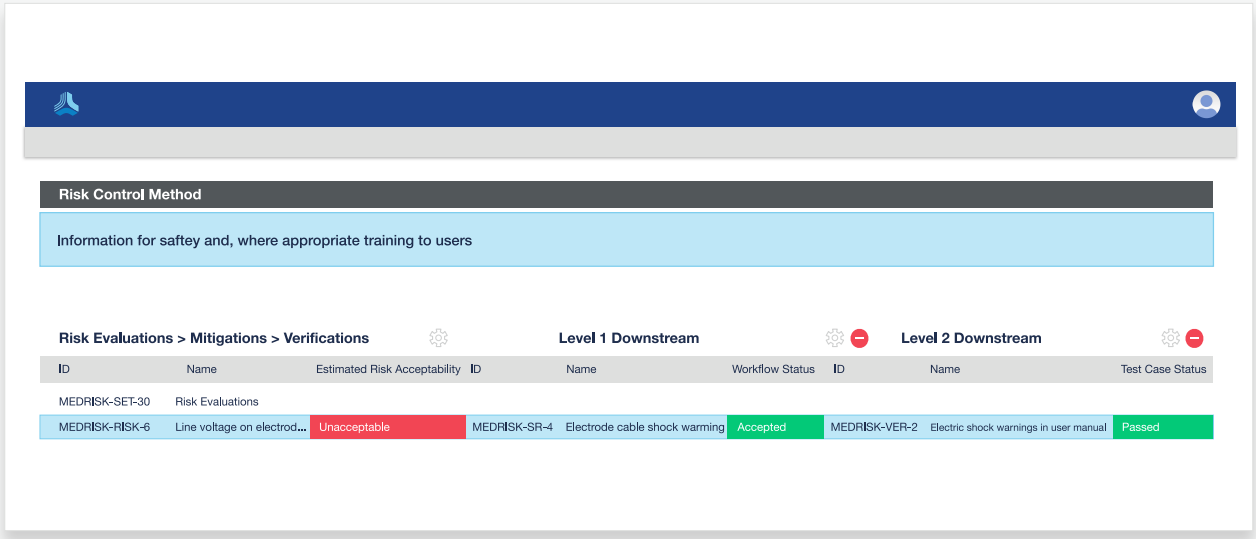
In Jama Connect, risk acceptability criteria can be customized for a particular product line or medical device classification in the risk management item. This acceptability may be standardized across projects to ensure consistency throughout the organization.

The risk evaluation item allows users to determine the probability that the hazardous situation occurs or results in harm to a patient by assigning a two-sided P value (probability value) and a severity value. The resultant P total and risk levels give teams an at-a-glance understanding of the risk level of each hazard.

Once defined, the risk acceptability can be determined such that the probability of the hazardous situation resulting in harm is accounted for during evaluation.

CLAUSE 7

# Risk Control




Clause 7 requires risk control measures to be developed, implemented and verified across the product development lifecycle. Risk control measures could include product design, preventative measures in the product and labeling. Residual risk must be evaluated against acceptability criteria, and risk control measures must be reviewed in case additional risks have been introduced inadvertently.

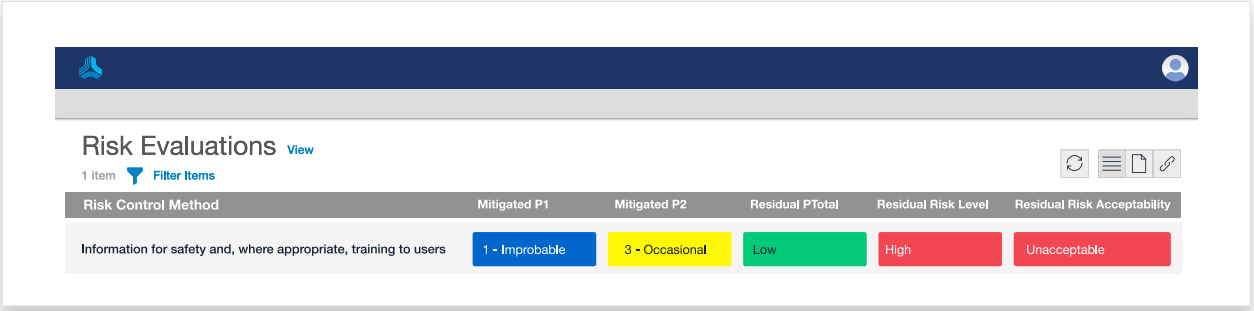
The risk evaluation item requires users to identify risk control options for a specific hazardous situation when the risk is deemed unacceptable. Control measures can include inherent safety by design, protective measures in the medical device or manufacturing process, and safety information.

Risk control measures, implementation verification, and verification of risk control effectiveness can also be accounted for in the risk evaluation item. Links to system requirements and verifications from hazardous situations to risk controls to verifications in Jama Connect can easily be created from the risk item to demonstrate traceability from hazardous situations to risk controls.

The residual risk evaluation process following implementation of risk controls can be captured within the risk evaluation item. Additionally, the item can be configured to include an evaluation of any new hazards introduced from the risk control measure, as specified in ISO 14971.

CLAUSE 8

# Residual Risk Evaluation




Clause 8 requires evaluation of the medical device's overall residual risk. If the overall residual risk is unacceptable, it must be demonstrated that the medical benefit outweighs the residual risk.

When defining risk control measures, teams can capture those measures in Jama Connect and link them directly to risks, then update the rankings to determine the residual risk level.

With traceability through all phases of risk, users can quickly identify potential pitfalls

in the product development process and address them before they become bigger barriers to success.

CLAUSE 10

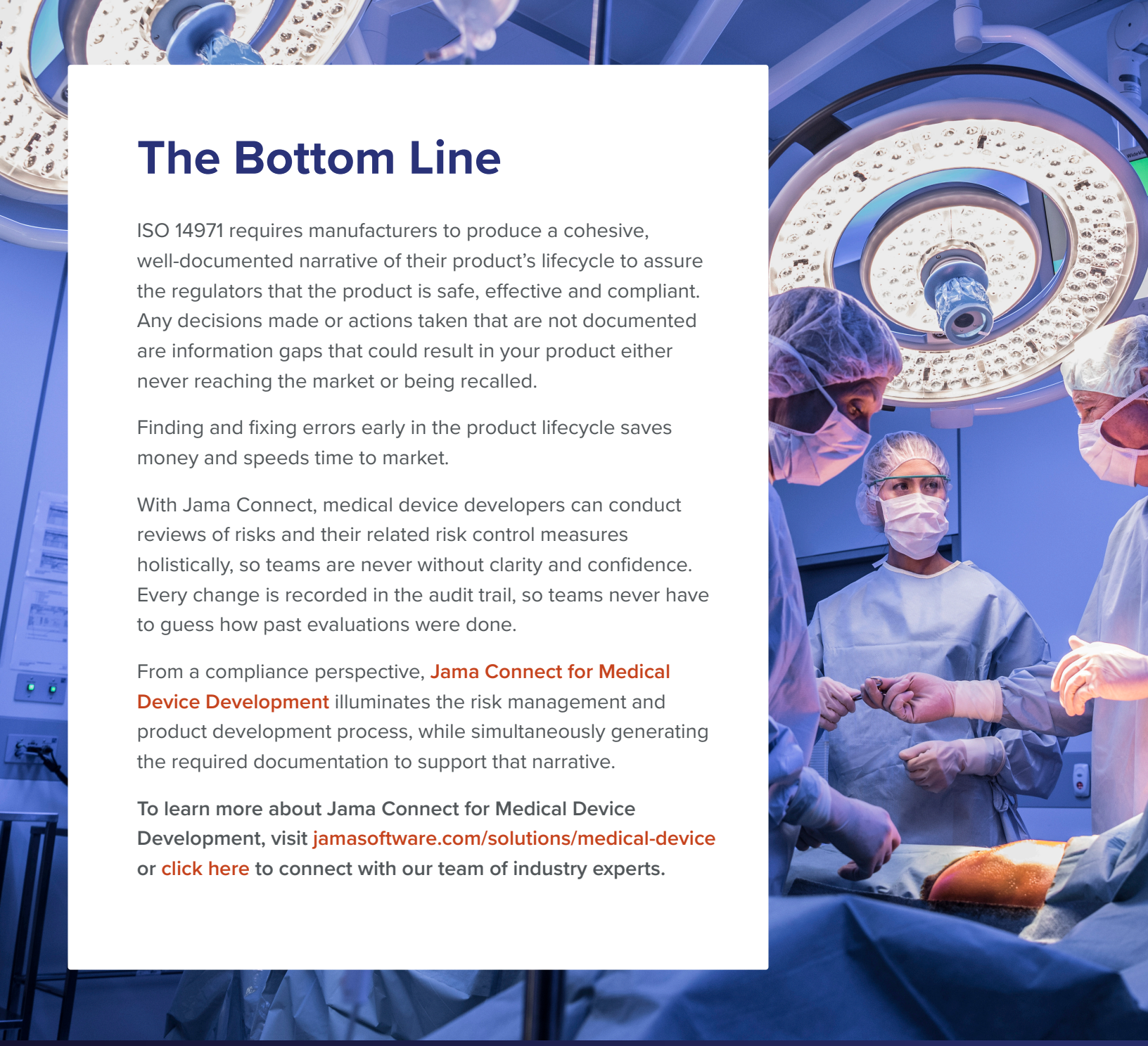
# Post-Production Risk Management Activities

Clause 10 of ISO 14971 outlines the post-production activities required by medical device manufacturers. Regardless of how your company chooses to collect and store the applicable information, Jama Connect can facilitate efficient and complete reviews. In Jama Connect, companies can add new failure modes, update occurrence or severity ratings based on market data, evaluate whether risks are still acceptable, and add and assess new controls for risks that are no longer acceptable. The results of these actions can be recorded in the system and relevant stakeholders can collaborate and review the activities in the Review Center.

Review of the risk management file is an ongoing activity, and using Jama Connect will ensure that this important requirement does not slip through the cracks while making the process much less burdensome.

Learn more about how Jama Connect can help accelerate medical device & life sciences development with our solution aligned to regulatory requirements.

> DOWNLOAD SOLUTION OVERVIEW



# The Bottom Line

ISO 14971 requires manufacturers to produce a cohesive, well-documented narrative of their product's lifecycle to assure the regulators that the product is safe, effective and compliant. Any decisions made or actions taken that are not documented are information gaps that could result in your product either never reaching the market or being recalled.

Finding and fixing errors early in the product lifecycle saves money and speeds time to market.

With Jama Connect, medical device developers can conduct reviews of risks and their related risk control measures holistically, so teams are never without clarity and confidence. Every change is recorded in the audit trail, so teams never have to guess how past evaluations were done.

From a compliance perspective, **Jama Connect for Medical Device Development** illuminates the risk management and product development process, while simultaneously generating the required documentation to support that narrative.

**To learn more about Jama Connect for Medical Device Development, visit jamasoftware.com/solutions/medical-device or click here to connect with our team of industry experts.**

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## ABOUT 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, please visit us at jamasoftware.com.