



# Jama Software for Medical Device Development

The Jama Product Development Platform helps teams manage the growing complexity of developing medical devices.



By bringing together Jama Connect™, Jama Analyze™ and industry-specific services, we help cross-functional medical device teams through the compliance process for their Class II and Class III medical devices. With Jama, customers can better manage device requirements, risks and design controls in one powerful platform, making regulatory submissions and audit preparations a straightforward process while adhering to FDA and ISO regulations.

# JAMA CONNECT:

## Navigate Medical Device Development Complexity



### Ensure Quality with End-to-End Traceability

Traceability increases efficiency, drives alignment and mitigates organizational risk. With Jama Connect, teams link and decompose high-level requirements to more detailed system and sub-system requirements to ensure proper verification and validation before release.



### Manage Risk Analysis

Manage risk analysis with the Jama Connect Risk Management Center, aligned with ISO 14971. The Jama Connect Risk Management Center helps teams identify risks earlier in development, saving teams from frustrating late-stage design changes and supporting the path to regulatory compliance.



### Maintain Audit Trails with Reports

Customizable, real-time reporting and baselining allows you to track all changes to information within the system, including timestamps and associated users. Data is easily exported from Jama Connect if your current process dictates storage of documentation in a quality management system (QMS).



### See the Impact of Change Quickly

Fine-grained impact analysis provides insights to make informed decisions as requirements evolve throughout the full development cycle.



### Conduct Reviews and Approvals

Increase early stakeholder visibility and participation in the review process to generate approval-ready content for e-signature.

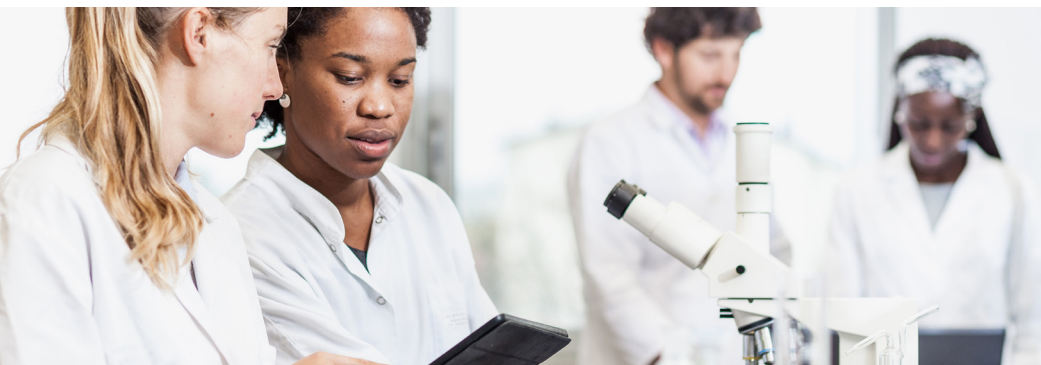


### Design Verification and Validation

Seamlessly manage traceability to test cases used for verification and validation, providing evidence to comply with government regulations and standards, like 21 CFR Part 820.

# JAMA CONNECT RISK MANAGEMENT CENTER:

## Identify and Mitigate Risk

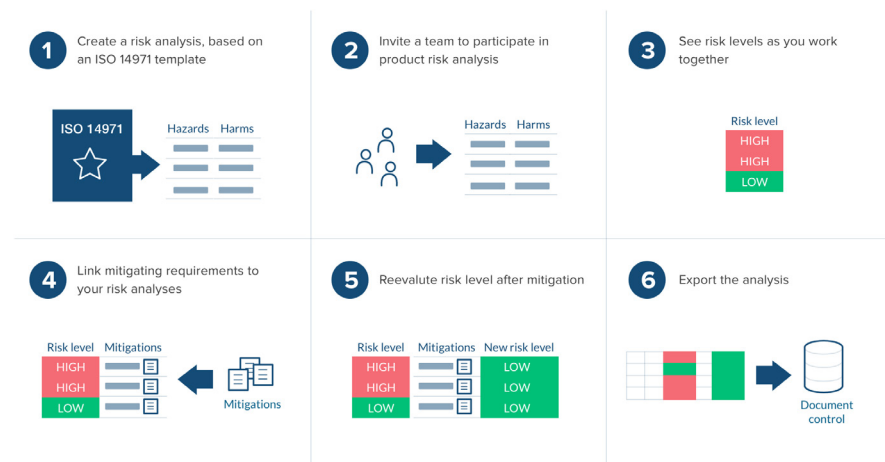


The Jama Connect Risk Management Center enables medical device developers to manage risk within the platform, in accordance with ISO 14971. Development teams can participate in risk assessment and risk mitigation, utilize risk plan templates, link mitigating requirements to your risk analyses. By working with live data, teams ensure they are viewing and properly mitigating risks, while maintaining confidence when moving to the next phase of development.

### What's Included:

- ✓ A standard template for compliance (aligned with ISO 14971)
- ✓ Custom templates that can be created, modified and locked for product- or class-specific use to assist with standardization
- ✓ Fast data entry in a tabbed format with hotkeys, allowing teams to focus on asking the right questions versus taking notes to be transferred into a spreadsheet later
- ✓ Information that saves automatically and persists across sessions
- ✓ Ability to link mitigating requirements to your risk analyses
- ✓ Option to export risk analysis and plan elements into formats like Microsoft Excel
- ✓ Features to filter and sort risk analyses to drive cross-functional conversations

### Six Steps to Success:



## MEDICAL DEVICE SERVICES: Streamline Your Development Process

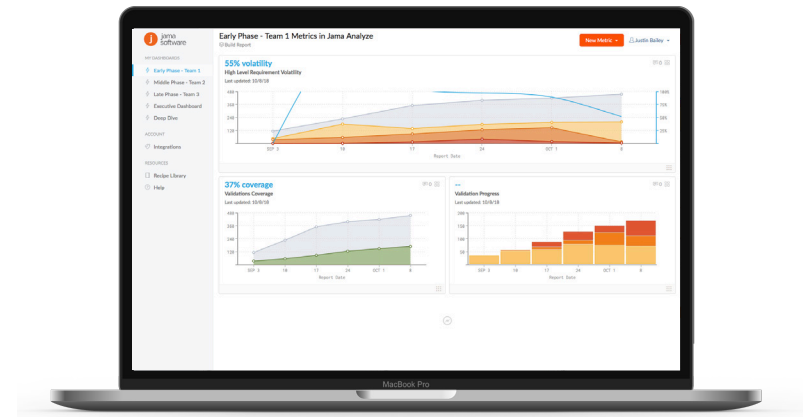
Jama's Medical Device Services ease the path to regulatory compliance by ensuring teams get ramped up quickly with Jama Connect based on a process tightly aligned to governing regulations ISO 13485:2016 and 21 CFR 820.30.

Medical Device Services include an out-of-the-box configuration of Jama Connect designed to reflect medical device development best practices, along with training and documentation templates for relevant design history file (DHF) assets.

### What's Included:

- ✓ Process documentation detailing how Jama Connect is best used to adhere to relevant parts of governing regulations ISO 13485:2016 and 21 CFR 820.30
- ✓ Out-of-the-box configuration for doing medical device development in Jama Connect
- ✓ Relevant templates to produce required documentation for your design history file (DHF), including design inputs, design control plan and traceability documents
- ✓ User training tailored to your process to get your team up and running
- ✓ Additional consulting to tailor Jama's approach to your unique needs and support your team as they begin working in Jama Connect

## JAMA ANALYZE: Gain Visibility and Enable Benchmarking



With Jama Analyze, medical device teams can track and trend detailed requirements and development data from Jama Connect to understand how projects are progressing from definition through build and testing. This adds more predictability to your development by plainly identifying what a good iteration or process looks like, enabling you to use that data to inform future development efforts.

Visit [jamasoftware.com](https://jamasoftware.com) to learn more about Jama Software for Medical Device Development.



## ABOUT JAMA SOFTWARE

[Jama Software](#) brings innovative analytics, solutions and insights to companies creating complex products and mission-critical software systems. With expanded product and service capabilities, the [Jama Product Development Platform](#) empowers large enterprises to accelerate development time, mitigate risk, slash complexity and verify regulatory compliance.

Representing the forefront of modern development, its rapidly growing customer base of more than 600 organizations — including Boston Scientific, Johnson & Johnson, Cochlear and Merck — use Jama Software to streamline processes and bring complex products to market. Through Predictive Product Development, Jama equips its customers to make the most of their revenue potential and achieve ongoing competitive advantages.