



SOLUTION OVERVIEW

Jama Connect for Medical Device Development

Accelerate innovation in medical device development, while adhering to industry regulations

Jama Connect for Medical Device Development helps medical device teams reduce the effort required to achieve regulatory compliance throughout the development process. With this solution, medical device teams can manage design controls for device requirements and related risks, simplifying regulatory submissions and audit preparations while accelerating time to market.

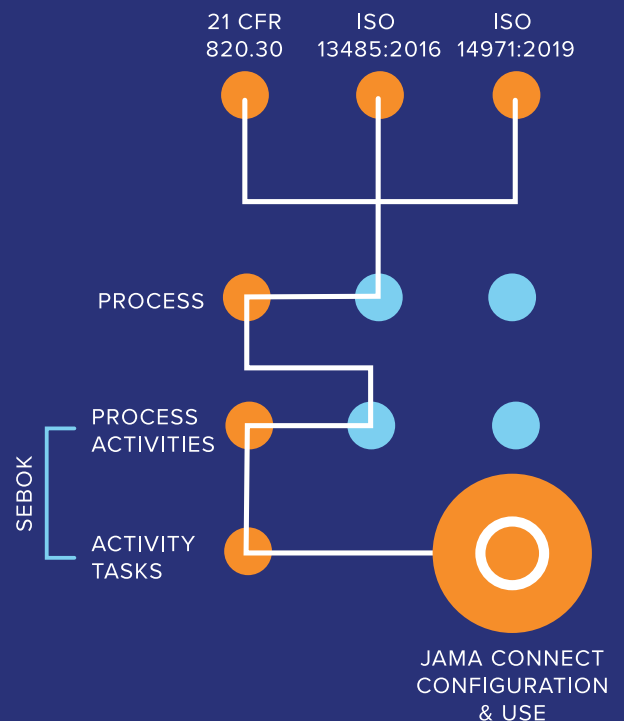
Accelerate Your Medical Device Development



Jama Connect for Medical Device Development is designed to help you get ramped up quickly with a platform, training and documentation aligned to industry regulations ISO 13485:2016, 21 CFR 820.30, and ISO 14971:2019, while applying a proven Systems Engineering approach to product development.

What's Included:

- Standard frameworks aligned to key industry regulations: ISO 13485:2016, 21 CFR 820.30, and ISO 14971:2019
- Procedure and configuration guides for medical device design control activities
- Export templates for the design history file (DHF) & risk management File
- Training and consulting designed for success within medical device development and risk management



A Single Platform for Managing Design Controls for Device Requirements and Related Risks



Easily Demonstrate Traceability

Traceability ensures that design inputs have been met and verified, providing necessary evidence from the design control process. Jama Connect allows you to easily produce traceability documentation required by regulators.



Manage Risk Analysis

Manage risk analysis, aligned with ISO 14971:2019. Jama Connect helps teams identify and mitigate risks earlier in development, saving teams from frustrating late-stage design changes and supporting the path to regulatory compliance.



Maintain Audit Trails and Export Data

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).



Reuse and Baseline Management

Compare versions of a requirement, generate branches to develop a variant, and create catalogs of reusable requirements to improve product development.



Compliant Reviews and Approvals

Increase early stakeholder visibility and participation in the review process with E-Signatures that are compliant with FDA 21 CFR Part 11.



Design Verification and Validation

Seamlessly manage traceability to verifications and validations, providing evidence to comply with government regulations and standards, like 21 CFR Part 820.30.

Optimize Success for Your Organization

When you purchase Jama Connect for Medical Device Development, our consultants partner with you to adapt the solution to fit your product delivery process and build adoption of Jama Connect within your organization.



Alignment Phase

The alignment phase aims to determine and implement the best use of Jama Connect for your organization based on an understanding of your product-delivery processes, business objectives and desired team workflow.

This phase includes:

Preliminary project planning and discovery sessions to understand your people, process and data as it pertains to requirements management, verification and validation, and risk management for medical device development

- Onsite workshop or remote working sessions focused on alignment of processes to governing regulations ISO13485:2016, 21 CFR 820.30, and ISO 14971:2019
- Consultants partner with you to determine exporting needs and properly configure standard templates to generate necessary documentation for your QMS
- Your Jama consultant will work with the core implementation team to prepare Jama Connect for use by end users, over a small number of remote working sessions if needed



Launch Phase

Once it's ready to use, your Jama consultant will lead a remote or onsite training to show your teams how to use Jama Connect. Following the training, your consultant will be available remotely to provide assistance as needed to support your initial implementation.



ABOUT JAMA SOFTWARE

Jama Software provides the leading platform for requirements, risk and test management. With Jama Connect for Medical Device Development, teams building complex products, systems and software improve cycle times, increase quality, reduce rework and minimize effort proving compliance. Representing the forefront of modern development, Jama's growing customer base of more than 600 organizations includes Boston Scientific, Johnson & Johnson, Abbott, and Merck.

www.jamasoftware.com