SOLUTION OVERVIEW

Jama Connect® for Digital Health

Accelerate innovation in digital health solutions, while adhering to industry regulations.

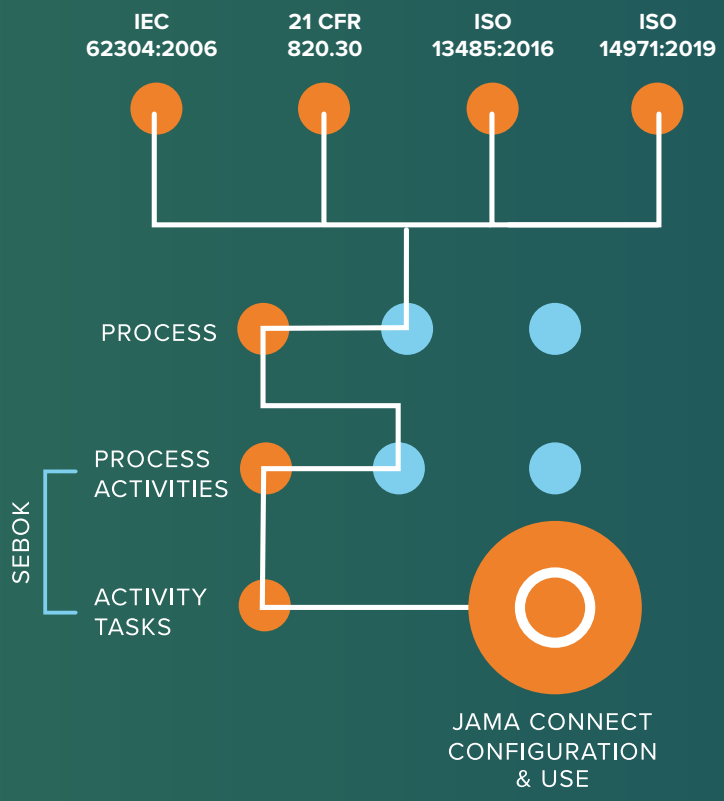
Jama Connect for Digital Health helps teams reduce the effort required to achieve regulatory compliance throughout the development process. With this Software as a Medical Device (SaMD) solution, development teams can manage design controls for device requirements and related risks, simplifying regulatory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

Accelerate Your Digital Health Solution Development

Jama Connect for Digital Health 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, IEC 62304:2006/AMD 1:2015 and ISO 14971:2019, while applying a proven Systems Engineering and Software Development Lifecycle approach to product development.

What's Included:

- Standard frameworks aligned to key industry regulations: ISO 13485:2016, 21 CFR 820.30, IEC 62304:2006/AMD 1:2015 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
- Medical device development and risk management training and consulting services provided by experienced industry professionals.



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

Easily Demonstrate Traceability

View Live Traceability™ between user needs and use cases, design inputs, system/subsystem requirements, design documentation, Software of Unknown Provenance (SOUP) / Off the Shelf (OTS) components, identified risks and failure modes, and verification and validation testing, and beyond. Jama Connect also allows you to easily analyze the impact of changes.

Manage Risk Analysis

Keep track of SOUP/OTS components and manage risks in alignment 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

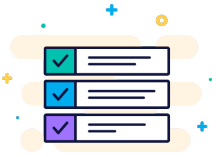
Real-time reporting and baselining allows you to track all changes to information within the system, including timestamps and associated users. Data is easily exported from Jama Connect if your current process dictates storage of documentation in a quality management system (QMS).

Reuse and Baseline Management

Compare versions of a requirement, generate and merge branches of different requirement variants, and create catalogs of reusable requirements to increase the efficiency and agility of your product development process.

Compliant Reviews and Approvals

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



Design Verification and Validation

Quickly identify gaps in testing coverage, analyze the impact of requirement changes, and generate the 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 Digital Health, our consultants partner with you to adapt the solution to fit your product delivery process and drive 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:

- Remote workings sessions or on-site workshops (on demand) focused on alignment of processes to governing regulations ISO 13485:2016, 21 CFR 820.30, IEC 62304:2006/AMD 1:2015 , 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

Launch Phase

Once it's ready to use, your Jama Software consultant will lead a remote or onsite training to show your teams how to use Jama Connect. Following the training, your consultant will continue to provide assistance remotely, and will help you adapt to future challenges.

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.