



Focus on Development Instead of Documentation with Jama Connect® for Software as a Medical Device

Developing Software as a Medical Device (SaMD) often involves a struggle to balance demanding documentation with highly iterative software development cycles under tight deadlines that are driven by market conditions. It can be burdensome to generate the records required by specific regional regulatory standards for medical software applications including: mobile health apps, clinical decision support systems, electronic health records, and remote patient monitoring platforms.

Jama Connect® for SaMD is a powerful requirements management solution framework developed by our team of medical device industry experts that alleviates the burden of documentation to allow your teams to focus on innovation and the efficient development of medical software products that are safe, effective, and compliant.

Key Benefits

Streamline Compliance

SaMD products must adhere to stringent regulatory and quality standards, such as ISO 14971, IEC 62304, 21 CFR Part 820.30, and FDA guidance on cybersecurity in medical devices if marketed in the United States and IVDR and MDR standards if marketed in the European Union. Jama Connect for SaMD provides a host of templates that can be customized with your company's style and content elements as required by your branding and quality management system.



Jama Connect Adheres to the Following Protocols

Built on Jama Software's Secure and Scalable Cloud Platform



Suitably validated by TÜV SÜD for safety-related development per IEC 62304



Jama Connect is SOC2 Type 2 certified in both the server and application



Ensures strong privacy management practices

TLS

Data transferred is secured and encrypted

Simplify and Demonstrate Complex Traceability

Software development cycles are very iterative, which increases complexity and makes tracking the effects of rapid and numerous modifications difficult. **Live Traceability™** in Jama Connect simplifies the process by enabling development teams to maintain proper traceability — both upstream and downstream — across the software development lifecycle to ensure that every software component and subcomponent, including third party Software of Unknown Provenance (SOUP)/Off the Shelf (OTS) software, meets all software requirements. Out-of-the-box templates that align with IEC 62304 and best practices ease the process of demonstrating traceability.

Facilitate Reuse and Sync

SaMD often involves developing parallel releases or variants that share many of the same requirements. Jama Connect allows you to efficiently reuse or sync requirements, hazards, risk assessments, and test cases between projects to significantly reduce redundancy. Teams can compare versions of a requirement, generate branches to develop and track a variant, and create catalogs of reusable requirements to improve product development. This minimizes errors, speeds up development cycles; and helps to ensure compliance with international standards.

Integrate Risk Management

Risk management for medical devices has historically involved a manual process using Microsoft Excel. Jama Connect for SaMD is a requirements management tool featuring built-in risk analysis compliant with ISO 19471 and failure modes and effects analysis (FMEA) that can identify risks earlier in the development process, saving teams from frustrating late-stage design changes.

Foster Efficient Reviews

Meeting deadlines for software development, approvals, and launches requires timely reviews to uncover issues, assess design tradeoffs, and ensure alignment with requirements. Jama Connect fosters efficient communication and reduces the time required for reviews by providing an intuitive, easy-to-use collaborative platform for stakeholders to provide feedback, track changes, and sign off on software development decisions. Teams can increase early stakeholder visibility and participation in the review process with E-Signatures that support compliance with FDA 21 CFR Part 11.

By leveraging Jama Connect, SaMD development teams can significantly improve their efficiency, reduce errors, enhance safety, and expedite development while maintaining the highest standards of quality and regulatory compliance.

To learn more, visit us at jamasoftware.com



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.

