Jama software

DATASHEET

jama connect®

Integrate Cybersecurity and Safety Risk Management in Jama Connect to Simplify and Accelerate Medical Device Development

Medical devices increasingly include software that can connect to the Internet and have vulnerabilities to cybersecurity threats. Under ANSI/AAMI SW96:2023, recognized by the FDA as an official standard for medical device cybersecurity, these fall under the definition of cyber devices in Section 524B which moving forward will require a cybersecurity risk management process. In addition, under the FDA's Medical Device Cybersecurity Final Guidance (Sept 2023), companies must include a software bill of materials (SBOM) in labeling for device users.

Cybersecurity risk management is a complicated process that involves identifying assets, estimating security risks, and determining and verifying the effectiveness of security risk controls to ensure that each security risk has acceptable levels of control. Companies must account for the interplay between cybersecurity and safety risks that may impact each other.

Faster, More Compliant Product Development with Jama Connect

Jama Connect for Medical Devices harmonizes cybersecurity and safety risk management to simplify complex risk evaluations while accelerating responses to threats. The out-of-the-box configuration integrates cybersecurity and safety risk management into the device maker's Product Development Process (PDP) and provides comprehensive cybersecurity and safety trace reports. Jama Connect may be used for SBOMs by customers creating their own configurations. Top global medical device & life sciences companies use Jama Connect to efficiently manage cybersecurity and safety risks, simplify regulatory submissions and audit preparations, and accelerate time to market.

KEY BENEFITS:

- **Reduce complexity and increase efficiency managing risks**
  Instead of separate solutions and documents for ANSI/AAMI SW96:2023 cybersecurity risk management and ISO 14971 safety risk management, choose a smarter and more efficient integrated approach by managing both in Jama Connect with risk-related items, workflows, and reports.
- **Manage change more holistically**
  Easily manage cybersecurity and safety risks by having a clear, holistic understanding of the impacts of changes made across the development process. An integrated solution provides the visibility needed to help avoid situations where risk controls designed (or changed) to reduce one type of risk would, in effect, increase the other type of risk.
- **Document traceability in a comprehensive way**
  Documenting comprehensive traceability between cybersecurity and safety is a best practice. Live Traceability™ in Jama Connect enables teams to trace cybersecurity risks back to potential safety risks of the device, thus providing a holistic risk management approach.

Cybersecurity Risk Management Elements Out-of-the-Box

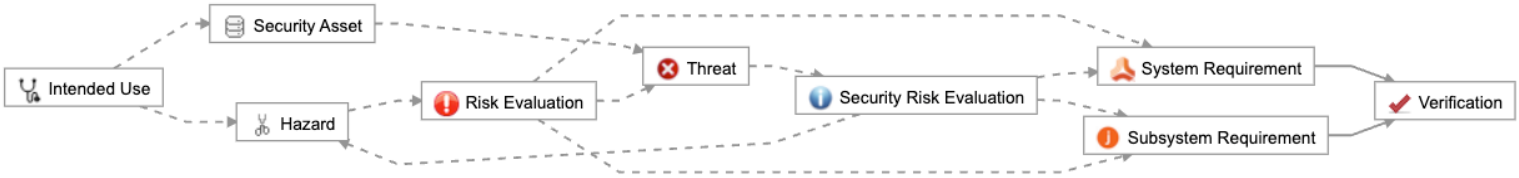
Jama Connect for Medical Devices provides Traceability Information Models (formerly known as Relationship Rule Diagrams) with pre-defined item types based on ANSI/AAMI SW96:2023:

- Intended use
- Applicable assets - software, operating systems, applications, firmware
- Identification of associated threats - vulnerabilities, threat scenarios
- Evaluation of security risks
- Risk controls
- Verification of control effectiveness

The Cybersecurity Trace Matrix report will show how security risks can be configured to your organization's processes and trace safety-related risks. It conveys the following:

- Security assets and characteristics
- Threats, security vulnerabilities, threat scenarios
- Security risk evaluation using exploitability & severity factors
- Security risk controls & verification of effectiveness
- Benefit/risk statements

Managing Cybersecurity Risks in Jama Connect for Medical Devices



Jama Connect is the only multi-tenant requirements management platform that offers a secure cloud solution designed for Medical Device & Life Science customers that need to validate their intended use of the system.

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

Compliant with all EU Privacy Shield Framework program requirements

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

Ensures strong privacy management practices

Data transferred is secured and encrypted

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.