DATASHEET

jama connect®

Streamline Medical Device Postmarket Surveillance by Taking a Full Lifecycle Approach with Jama Connect®

Postmarket surveillance (PMS) is an expected regulatory activity that plays a vital role in ensuring the safety and effectiveness of medical devices after they reach the market. The key to an effective PMS program is to ensure that the requirements and risks identified early in the development process are continually updated throughout the product's lifecycle. Maintaining "living" design documentation allows companies to better identify, analyze, and respond to potential safety issues. As new information about the product comes from user feedback, clinical studies, or complaint reports, teams can review and update all product information in Jama Connect, allowing them to conduct better investigations and continually enhance the product as a benefit to patients.

Jama Connect for Medical Devices streamlines and simplifies the PMS process by providing a single source of truth for a product's entire lifecycle. Whether it is managing requirements, performing risk analyses, or conducting effective change management, companies can meet all regulatory requirements and provide patients with safer and more effective devices.

Seamlessly Transition from Development to Surveillance

Jama Connect's ability to create Live Traceability™ across your development tool chain ensures that every step, from ideation to postmarket adjustments, is documented and traceable.

Organizations that use Jama Connect for managing requirements, tests, and risk during development and postmarket surveillance can conduct investigations and implement product changes with greater speed and confidence to minimize the impact on patients and the company.

KEY BENEFITS:

Improve Postmarket Surveillance by Using the Same Platform During Development and Post Launch

Jama Connect is a full lifecycle platform that allows companies to manage requirements, testing, and risk analyses both during development and after launch, ensuring all PMS activities are managed efficiently and reliably.

Enhance Risk Management Through Structured Collaboration

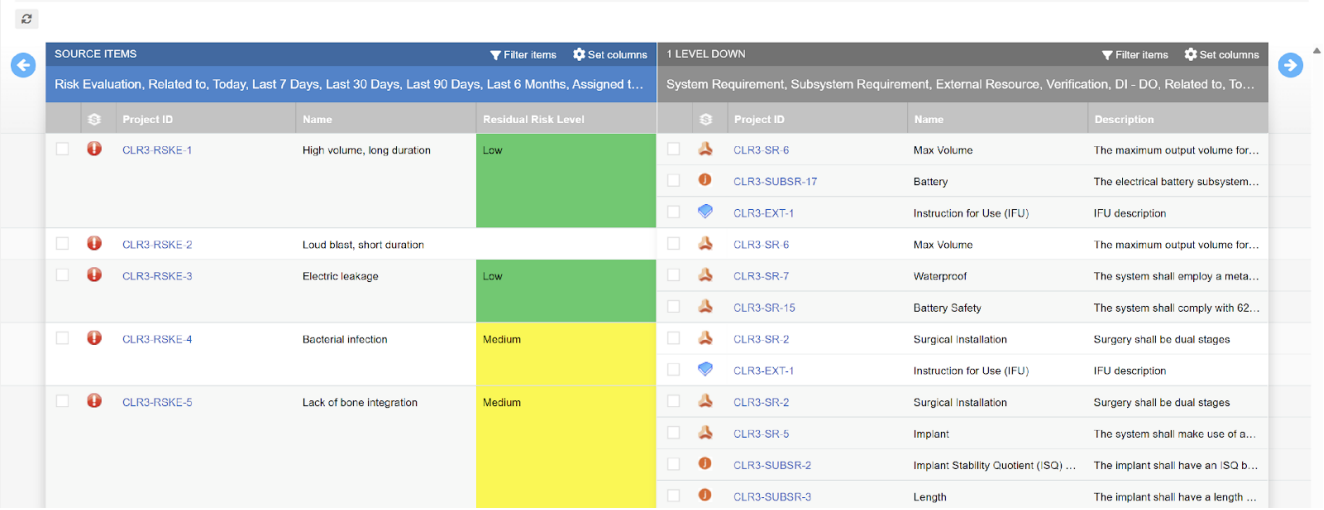
Build or easily migrate risk management items into Jama Connect so that internal and field-based teams can work together to collect and analyze product safety information and implement better corrective and preventive actions faster.

Modernize Change Management by Maintaining a Living Design Documentation File

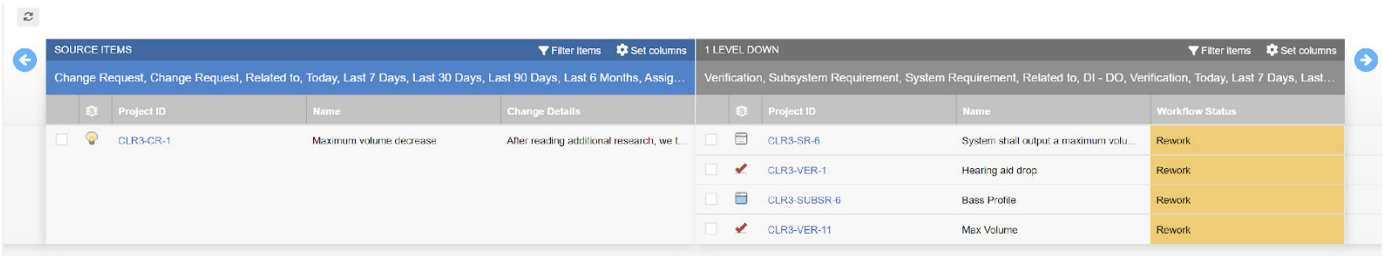
Create a real time view of all product design and risk information in Jama Connect and utilize automated workflows to conduct change management activities.

Finding success in Jama Connect is not just limited to those starting a new project from scratch. A company with many existing projects can transfer all requirements and risk information using migration solutions and services provided by Jama Software. This will create a strong foundation that helps the organization enhance postmarket surveillance activities and improve future development.

Risk Evaluation Live Traceability



Change Request Live Traceability



Jama Connect is the only multi-tenant requirements management software 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

Jama Software® complies 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.