DATASHEET

Streamline FDA CSA Using jama connect to Validate Software Supporting Medical Device and Life Science Manufacturing and Quality

Software used directly or in support of medical device manufacturing or quality systems must be validated to be fit to perform as intended under FDA 21 820.70(i): Production and Process Controls. The FDA recommends a Computer Software Assurance risk-based approach that involves articulating the intended use of software including any custom configurations, determining the risk and appropriate effort level for validation, and documenting all analysis, decisions, and testing in a form that can be shown to auditors. In Life Sciences, clinical research organizations have similar processes to prove that their processes and tools are in a validated state.

Using a document-based approach reliant on Word or Excel for managing your computer software assurance process is inefficient and error-prone, risking penalties for non-compliance. A smarter, more efficient solution is Jama Connect® for Medical Devices and Life Sciences.

Jama Connect is used by top global medical device & life sciences companies to efficiently manage design controls for device requirements and related risks, simplify regulatory submissions and audit preparations, and accelerate time to market.

Key Benefits

Get the most out of your requirements management solution
Use the same Jama Connect solution for managing and documenting your product requirements AND your computer software assurance validation process to maximize your ROI.

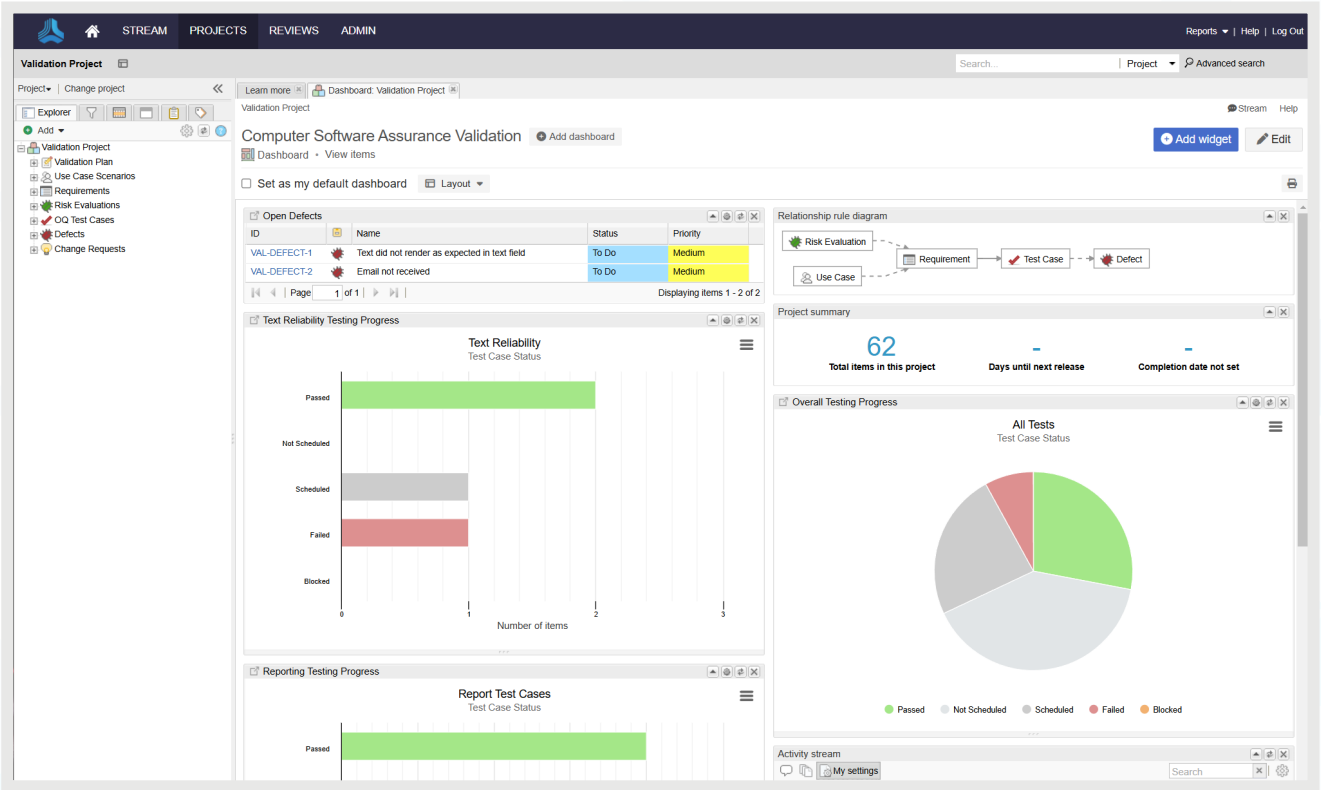
Save time through risk-based approach to validation
Streamline your computer software assurance validation effort by using Jama Connect's ability to track changes to revalidate only what's changed.

Accelerate preparation of documentation
Instead of manually copying, pasting, and formatting data in Excel or Word documents to create documentation that can be shown to auditors, take advantage of the built-in reporting capabilities of Jama Connect.

Enable easy collaboration by internal teams and contractors
Jama Connect's Review Center and collaboration functionality makes it easy for validation, quality, compliance, IT, and other internal teams as well as external contractors to contribute to software validation and documentation.

Simplify the validation of Jama Connect
Jama Software® makes it easy to validate Jama Connect based on the intended use with the Jama Connect Validation Kit and the Customer Validated Cloud environment options.

Using Jama Connect for Computer Software Assurance Validation



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

Ensures strong privacy management practices

Data transferred is secured and encrypted

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.