



## Validation Kit for Medical Device and Life Sciences

### Ease the Challenges of Validating Jama Connect®

Medical device and life sciences companies may need to validate their use of Jama Connect® (depending on their intended use(s) of the system) regardless of whether it is predicated on regulatory guidelines, such as:

- **ISO 13485: 2016**
- **21 CFR 820.70 Production and Process Controls**
- **FDA Draft Guidances: General Principles of Software Validation (2002) and Computer Software Assurances (2022)**
- **Internal organization quality and governance processes**

The Validation Kit for Jama Connect is designed to reduce the time and resources required for validation by providing a complete list of Jama Software®'s internal mechanisms, workflows, usage scenarios, and test cases that are used in the process of internal validation activities in obtaining our TÜV SÜD Validation Certificate.

The kit is also designed to radically reduce the amount of time it takes for Jama Software customers to perform their own validation and is often purchased as part of the [Jama Connect Validated Cloud Package](#) and in conjunction with a [Jama Software Success Program](#), which includes the following validation services:

- **Jama Connect Validation Kit Training**
- **Jama Connect Migration to Customer Validated Cloud**
- **Validation Release Notes Consultation**
- **Validation Guidance**

Review the table below to see what's included when you purchase the Validation Kit for Jama Connect.

### Use the Validation Kit for Jama Connect to Streamline Your Process

- Shorten the time it takes to validate Jama Connect, and ongoing incremental feature enhancements, in safety-critical environments.
- Define safety-critical workflows for clear starting points instead of starting from scratch.
- Validate in cloud and self-hosted environments.



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

Artifact	Benefit
<b>Installation Qualification (IQ) Report</b>	A customer-specific installation qualification report reflecting the steps required to create new Jama Connect instances.
<b>TÜV SÜD Certificate and Report</b>	Jama Software is certified by internationally-recognized testing body TÜV SÜD as suitable for use in the development of safety-related software according to IEC 62304. Jama Software provides a certification by TÜV SÜD for each cloud and self-hosted release.
<b>Process Document:</b> Provides a detailed description of the product development process and lifecycle for Jama Connect.	This document provides insight into how we ensure quality throughout Jama Connect’s development process and lifecycle.
<b>Critical Workflows (Safety Manual):</b> Validates a release of Jama Connect.	This dictates the intended use of the solution in a functional safety environment, highlights assumptions, and outlines core workflows, or critical paths, through Jama Connect.
<b>Performance Qualification Report:</b> Provides an overview of the completed release’s regression, highlighting the impacted areas, testing environments, and performance results. It includes a summary of test results. It also includes Regression Database Compare Results, which compares the databases of the soon to be released version and the previous version, including added tables, removed tables, and structural changes.	The tests are derived from core workflows, so companies can compare between each release and their own internal documentation of intended use to assess what areas need additional testing. This critical document helps you reduce time spent on validation.
<b>Importable Core Workflows and Test Cases</b>	<p>Companies use Jama Connect to validate that all tools they use in their safety-critical processes are performing correctly. If you want to use Jama Connect to validate itself, we include importable core workflows, test cases, and steps for many of these test cases.</p> <p>The test cases provide a baseline to build your own test plans, and further streamline validation by aligning Jama Connect test plans with yours.</p>
<b>PQR Testing Details</b>	Provides the regression testing results sorted by test case ID and includes all runs and results for each test case.
<b>Team Coverage Report:</b> Highlights sprint teamwork for the current release.	Test cases created for new functionality in the current release.
<b>Test Cases Comparison Report</b>	It is a baseline comparison report that highlights the updated, removed, and added test cases between the two most recent releases.

Access to the Validation Kit for Jama Connect also includes access to a private area of the Jama Community where you can view all of the documentation and updates for each release. In this community you'll also find:

Artifact	Benefit
<b>Known Defects</b>	A list of deferred defects tied to core workflows, from medium to critical severity. As a part of the service, the Jama Software team publishes bugs discovered between releases. While we aim to fix defects as soon as possible, knowing potential workarounds is key for documentation and communication with users.
<b>Customer Feedback Forum</b>	Here, you can provide feedback on core flows. As new functionality is added or your processes change, we want to know what we should consider as a part of our internal validation activities.

## Interested in learning more?

Connect with us here: [www.jamasoftware.com/trial](http://www.jamasoftware.com/trial)



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. Visit us at: [jamasoftware.com](http://jamasoftware.com)