

 **jama connect™**  
**Software Validation Services**

**Accelerate Validation Using Templates, Frameworks,  
and Expert Services**

Jama Connect Software Validation Services provides an approach for software validation that is optimized to the intended use of the Jama Connect Software Validation Services for Medical Device Development and is adaptable to any customer's development process.

ISO/TR 80002-2:2017 requires manufacturers to validate software applied to their quality management system. For customers who have not yet validated Jama Connect for use in their medical device development process, Jama Connect Software Validation Services for Jama Connect provides a structured approach to meet this validation requirement.

This service provides assistance to implement and manage the software validation plan, intended uses, software use requirements, software functional requirements, verifications, and risk control measures.

Additionally, templates and frameworks are provided that align to our approach for Medical Device Development (based on ISO 13485, 21 CFR 820.30, and ISO 14971) as a time-saving starting point.

Our consultant will work with your team to modify these standard templates and frameworks to align with your intended use of Jama Connect. This work will culminate in a finalized Validation Plan and a defined process to perform recurring validation.

We also offer assistance optimizing a customer's current approach for validating Jama Connect or assuming the execution of ongoing validation activities. Generally, this includes a detailed assessment of current practices, review of the system in use, and reimplementation using Jama Connect for managing validation activities.

### KEY BENEFITS:

- **Fast track initial validation using Jama's Connect's templates, frameworks, and expert services aligned to medical device development industry standards and regulations including: ISO 13485, 21 CFR 820.30, and ISO 14971**
- **Leverage your existing investment in Jama Connect to document your validation, and manage validation and ongoing re-validation activities**
- **Reduce the ongoing validation effort by leveraging the Jama Software team to execute validation plan verification**
- **Utilize the Jama Connect Validation Kit that is TÜV SÜD certified fit-for-purpose**
- **Satisfy the requirements of validating software applied to QMS (ISO/TR 80002-2:2017)**

## Services Included:

OPTION	USE CASE	WHAT'S INCLUDED
Software Validation Plan and Set-up	Customers who have not yet validated Jama Connect for use in their development process	<ul style="list-style-type: none"><li>● Templates and frameworks aligned to medical device development (based on ISO 13485, 21 CFR 820.30, and ISO1497)</li><li>● The consultant will work tailor the solution to align with your intended use</li><li>● This work will culminate in a finalized validation plan and progress into the validation process</li></ul>
Transition and Optimize Validation Process	Customers with a current approach to software validation	<ul style="list-style-type: none"><li>● Assessment of current practices</li><li>● Re-implementation using Jama Connect for managing validation activities</li></ul>
Jama Connect Validation Kit	Part of each product release to include evidence and documentation with validation that is TÜV SÜD certified per ISO 62304	<ul style="list-style-type: none"><li>● Process Document</li><li>● Critical Workflows (Safety Manual)</li><li>● TÜV SÜD Certificate and Report</li><li>● Performance Qualification Report</li><li>● PQR Testing Details</li><li>● Team Coverage Report</li><li>● Test Cases Comparison Report</li><li>● Known Issues: list of known defects</li></ul>
Validation Execution (recurring)	Jama Software consultants will execute the verifications aligned to the software requirements and intended uses	<ul style="list-style-type: none"><li>● Initial validation executed with alignment to the software requirements and intended uses</li><li>● Maintenance and re-validation</li></ul>

Because everyone requires clarity on what your teams are building and why, Jama Connect Software Validation Services offers packaging that is flexible to meet your needs:

- Custom scoped to align to customer requirements
- One-time implementation and set-up based on total estimated effort for a fixed fee
- Annual subscription for execution and re-validation, scoped based on activities and frequency of the re-validation activity

Contact Jama Software to learn more about Software Validation Services for Jama Connect or visit: [jamasoftware.com/solutions/services](https://jamasoftware.com/solutions/services)



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](https://jamasoftware.com).