Jama software®

DATASHEET

jama connect® for Medical Device & Life Sciences Development

Accelerate innovation in medical device development, while adhering to industry regulations

Jama Connect® for Medical Device and Life Sciences Development Solution's license model is fully scalable, ensuring rapid deployment and easy adoption of the solution across your product development team. The base product includes the full breadth of Jama Connect's core capabilities with access for up to 10 named Creators, and site licenses for Stakeholders and Reviewers — enough to get your product organization up and running with our industry-leading solution.

Additionally, the solution is designed for medical device and life sciences developers and includes: standard frameworks aligned to key industry regulations, procedure and configuration guides, export templates for design history files (DHFs), risk management files, and other technical files. The solution also includes optional training and consulting for medical device and life sciences development.

The solution allows flexibility to include a range of Creator licenses, such as:

- **10 named Creator licenses (or an equivalent mix of named and floating Creators)**
- **Note: 4 named Creator licenses can be exchanged for 1 floating Creator license. For example, instead of 10 named Creator licenses you can have 1 floating and 6 named Creator licenses.**

The base product can easily be extended to allow access for the entire enterprise. Jama Connect is available as either a cloud or self-hosted deployment option and is based on an annual subscription. Jama Connect does not require client-side software to be installed.

Includes:

- Access for up to 10 named Creators
- Unlimited access for all Stakeholders and Reviewers
- Secure SaaS hosting with SOC2 Type 2 certification in both the server and application
- 24 x 7 critical issue support
- Non-production-hosted sandbox
- Out-of-the-box frameworks aligned to key industry regulations: ISO 13485:2016, ISO 14971:2019, 21 CFR 820.30, IEC 62304, EU MDR, and IVDR
- Procedure and configuration guides for medical device design control activities
- Standard reports to support design history file (DHF) and risk exports
- Optional training and consulting
- Out-of-the-box framework for Life Sciences and Research Use Only (RUO) projects
- The option to add our Validated Cloud Package for organizations that need to validate their use of Jama Connect to meet requirements.

The following report / export templates are provided as part of the solution to support alignment to industry standards and regulations within the medical device industry.

Report / Export Templates Included:

Our team is here to help customize these templates to meet your organization's unique needs.

TITLE	DESCRIPTION
Design and Development Plan	Records project overview and plan documentation
Intended Use Document	Documents the indended use statement(s)
Design Input	Documents system and subsystem requirements
Design Output	Documents design output items
Trace Reports	Documents general traceability of design including: • User Needs to design validation • Requirements to design verification
Verification / Validation Plan	Documents V&V plan, and test steps
Verification / Validation Results	Documents V&V test run information
Change Request	Document of change request
Change Request Supplemental	Baseline comparison report of change request baselines (before and after)
Risk Management Plan	Documents risk management plan and strategy
Risk Analysis Trace Report	Documents risk trace, including hazards, risk level, risk control, and benefit/risk analysis
FMEA Trace Report	Document FMEA trace including failure mode, cause, risk, and mitigations

Success Programs

Customer Success Programs are designed to provide implementation, optimization, and consulting services to support ongoing Jama Connect use. They include initial implementation and installation services, administration training, hands-on guidance for tailoring Jama Connect to meet specific customer needs, end-user training, and customer-specific training materials.

Because everyone requires clarity on what your teams are building and why, Jama Connect offers four unique license types to suit different user needs and promote deep collaboration and alignment across your organization. The table below summarizes these available license types.

		User License			Additional License
	CAPABILITIES	CREATOR	STAKEHOLDER	REVIEWER	TEST RUNNER
WRITE	Create projects	●			
	Add and manage requirements	●			
	Create reports and dashboards	●			
	Initiate reviews	●			
	Create test cases	●			
	Write / edit test plans	●			●
	Execute test runs and log defects	●			●
READ / COMMENT	Read access	●	●		●
	View reports and dashboards	●	●		●
	Comment within project	●	●		●
	View activity stream	●	●		●
	Participate in collaboration stream	●	●		●
REVIEW	Participate in reviews	●	●	●	●
	Provide feedback and changes	●	●	●	●
	Add electronic signature	●	●	●	●
	Reply to collaboration stream	●	●	●	●