Jama software®

DATASHEET

jama connect®

for Medical Device Startups

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

Jama Connect® for Medical Device 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 5 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 developers and includes: standard frameworks aligned to key industry regulations, procedure and configuration guides, export templates for the design history file (DHF) & risk management file, and training and consulting designed for medical device development. Enhancements provided to all these components are provided in the subscription package.

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

- **5 named licenses**
- **2 named licenses and 1 floating license**

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 5 named Creators**
- **Unlimited access for all Stakeholders and Reviewers**
- **Secure SaaS hosting**
- **24 x 7 critical issue support**
- **Non-production-hosted sandbox**
- **Out-of-the-box standard frameworks aligned to key industry regulations: ISO 13485:2016, ISO 14971:2019, and 21 CFR 820.30**
- **Procedure and configuration guides for medical device design control activities**
- **Standard reports to support design history file (DHF) and risk exports**
- **Training and consulting designed for medical device development**

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:

TITLE	DESCRIPTION
Design and Development Plan	Contains project overview and plan documentation item types.
Design Inputs	Contains all accepted system and subsystem requirements.
Design Outputs	Contains all accepted design output items.
Verification / Validation Plan	Contains Validation or Verification plan with details and test steps.
Verification / Validation Results	Contains test run information by test plan.
Trace View	Generates CSV export of trace.
Trace Report	Generates Excel export of trace (pre-configured for levels and fields).
Change Request	Export of change request item.
Change Request Supplemental	A baseline comparison report of change request baselines (before and after rework).
Risk Management Plan	Generates Word or PDF export of Risk Management Plan document.
Risk Analysis Plan	Generates Word or PDF export of Risk Analysis Plan document.
Intendend Use Document	Contains all accepted intended uses.
Overall Acceptability Document	Generates Word or PDF export of Overall Risk Acceptability document.
Risk Analysis Trace Report	Generates an export showing traceability for each Hazard > Risk Evaluation > Risk Control Measures > Verification and Validation

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

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	●	●	●	●