

CUSTOMER STORY

Sim&Cure Enhances Regulatory Confidence and SaMD Innovation with Jama Connect®

ABOUT SIM&CURE

Sim&Cure is a medical technology startup developing advanced Software as a Medical Device (SaMD) for neurovascular procedures. Their solutions help clinicians plan and execute complex treatments, driving patient safety and effectiveness in a highly regulated field.

CUSTOMER STORY OVERVIEW

Delivering innovative neurovascular solutions requires Sim&Cure to meet strict regulatory standards and ensure smooth collaboration across its teams. Initially, requirements and traceability were handled manually in Word and Excel, which made it hard to coordinate, increased the risks of errors or missed gaps, and slowed down audits and compliance preparation.

Following a thorough evaluation of eight platforms, including requirements management tools and all-in-one QMS solutions, Sim&Cure chose Jama Connect. While Jama came at a higher price, the decision was driven by its unmatched regulatory reporting flexibility, robust traceability, and open API. Jama Connect enabled Sim&Cure to seamlessly integrate automated test results and coverage data directly into their requirements management process, allowing for real-time verification and ongoing compliance tracking. In contrast, other solutions did not offer the same adaptability for regulatory reporting, or the fine-grained traceability needed to satisfy dynamic audit and compliance demands. These advantages of Jama Connect gave Sim&Cure the confidence and control to formalize every step of development and support audit readiness.

CHALLENGES

Manual, Fragmented Processes

Reliance on Excel and Word for traceability and requirements created inefficiencies and increased the risk of missed or inconsistent documentation.

Inconsistent Abstraction and Impact Analysis

Requirements were detailed at varying levels, making it hard to analyze impacts or track changes comprehensively.

Slow Reporting and Audit Prep

Building audit reports and formal compliance evidence was manual and time-consuming, which risked delays in regulatory submissions.

WITH JAMA CONNECT, USERS EXPERIENCE:

- **Live Traceability™** providing end-to-end visibility and real-time impact analysis for compliance and audit readiness.
- **Configurable reports and templates** that simplify compliance while supporting regulatory requirements.
- **Open APIs** connecting automated test data directly to requirements and risk records.

“With Jama Connect, we know everything is covered according to standards like ISO 14971 and IEC 62304. The other solution’s reporting was less adaptable, but Jama lets us demonstrate compliance with confidence.”

Frédéric Ben Naïm, Software Quality Manager, Sim & Cure

“The partnership with Jama [Software]’s experts was a game changer for us. As a startup, you have one shot to get it right, and their guidance helped ensure we built our processes correctly from day one.” “Now, our teams truly collaborate from a single platform, and we’ve dramatically reduced the risk of errors—everyone can see we’re moving forward together,”

Frédéric Ben Naïm, Software Quality Manager, Sim & Cure

SOLUTION

Sim&Cure adopted Jama Connect to build a unified, audit-ready development system that delivers full traceability and regulatory oversight.

Centralized Traceability and Impact Analysis

Jama Connect serves as a single, reliable source of truth for requirements, risks, and verifications, letting teams see immediately how any change cascades through the project.

Superior Regulatory Reporting Compared to Competition

Jama Connect stood out during evaluation for its ease in producing flexible, regulator-ready reports. Audit documentation is generated in minutes using tailored templates, and permissions and traceability are fine-tuned for each team’s needs.

Seamless Integration for Compliance

The platform’s well-documented API enabled Sim&Cure to connect their automated test results and coverage data directly to requirements, streamlining verification and creating a living record of compliance.

Implementation Support and Best Practices

From the outset, Sim&Cure worked with Jama Software’s services team to design clean workflows and relationship structures, based on medical device best practices. This made onboarding and team training smooth and efficient.

OUTCOMES

Regulatory Confidence

End-to-end traceability and structured reports mean Sim&Cure is always ready for audits and aligned with key medical device standards.

Team Collaboration and Oversight

All teams share a centralized platform, making it easier to monitor and manage progress at every stage.

Faster, Error-Free Reporting

Automated, customizable reports and easy traceability have reduced reporting effort and improved documentation accuracy.

Focus on Product Value

With compliance streamlined and secure, engineering and design teams have more time to dedicate to product improvements and patient outcomes.