Jama software®

BrightInsight»

BrightInsight Revolutionizes Cybersecurity Risk Management with Jama Connect®

ABOUT BRIGHTINSIGHT

BrightInsight is a trusted partner for top life sciences companies, delivering regulated digital health solutions like Software as a Medical Device (SaMD) that transform patient care. In collaboration with leading BioPharma and MedTech firms, BrightInsight has developed pioneering solutions across more than 11 therapy areas.

CUSTOMER STORY OVERVIEW

Operating in a highly regulated industry, BrightInsight navigates strict deadlines, complex regulatory requirements, and dynamic client expectations. To maintain its competitive edge, the company needed a robust requirements management tool to refine its processes. A key challenge was integrating cybersecurity into its overall patient safety risk management framework.

By implementing Jama Connect, BrightInsight created a novel, integrated approach to risk management. This allowed them to automate traceability, optimize documentation, and significantly improve project efficiency. As a result, BrightInsight has reduced risk assessment activities by more than 50% and accelerated project timelines, all while ensuring comprehensive cybersecurity and patient safety.

CHALLENGES

Before implementing Jama Connect, BrightInsight faced several industry-wide challenges that hindered its ability to innovate safely and efficiently.

- **Fragmented Risk Management:** Managing cybersecurity and patient safety risks in separate streams resulted in disjointed assessments. This separation made it difficult to understand the true impact of a cyber threat on patient health.

- **Inefficient Documentation:** Manual processes using Word and Excel were inefficient, prone to error, and limited collaboration across global teams.

- **Cumbersome Traceability:** The document-first approach made tracing relationships between requirements, risks, and test cases a time-consuming manual task, often delaying regulatory submissions and product launches.

WITH JAMA CONNECT, USERS EXPERIENCE:

- Ability to seamlessly link cybersecurity risks to patient safety hazards, creating comprehensive risk models that improve safety and compliance.

- Optimized workflows and reusable requirement repositories help users reduce project timelines by months, expediting product launches and increasing efficiency.

- Real-time feedback tools and robust traceability features streamline collaboration while ensuring audit-ready documentation that impresses regulators.

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> *"We've been able to link cybersecurity risks back into patient hazards, which is something many companies struggle to do. Jama Connect's traceability and item relationships make that possible."*
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> **Lucas Holt,
> Director of Systems
> Engineering, BrightInsight**

> *"Jama Connect really forces you to think about traceability right from the get-go of the project, where in the old way of doing it, traceability was often an afterthought. It's the right way to do it."*
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> **Lucas Holt,
> Director of Systems
> Engineering, BrightInsight**

> *"The reusability of items, requirement sets, and risk management really shines for us, it has significantly reduced our design cycles."*
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> **Lucas Holt,
> Director of Systems
> Engineering, BrightInsight**

SOLUTION

BrightInsight leveraged the powerful features of Jama Connect to build a unified and efficient development process, with a groundbreaking approach to risk management.

A Novel Approach to Cybersecurity Risk

The most significant change was integrating cybersecurity directly into patient safety risk management. Using the powerful traceability features in Jama Connect, BrightInsight linked cybersecurity threat models directly to patient hazards. This innovative structure allows them to create comprehensive risk models connecting assets, vulnerabilities, and threats to specific patient safety outcomes.

Item-Based Management for Seamless Traceability

Jama Connect's item-first approach enabled BrightInsight to manage traceability from the very beginning of a project.

Optimized Reuse and Standardization

BrightInsight created reusable requirement repositories, particularly for common elements like cloud-based services. New projects can now pull from this "off-the-shelf" library of pre-built modules with fully linked requirements, risks, and testing frameworks.

Streamlined Reviews and Collaboration

Jama Connect's Review Center replaced lengthy meetings with real-time, asynchronous collaboration. Teams can now access shared projects, provide feedback, and monitor revisions, dramatically improving review timelines.

OUTCOMES

Since implementing Jama Connect, BrightInsight has achieved measurable improvements, solidifying its position as an industry leader.

- **Faster Cybersecurity Risk Assessments:** By integrating and standardizing its processes, the team reduced the time for cybersecurity and patient safety risk evaluations from six weeks down to just two.

- **Boosted Overall Efficiency:** Optimized workflows have expedited product launches, allowing BrightInsight to reduce project timelines by three to six months for its pharma clients.

- **Enhanced Regulatory Confidence:** During audits, BrightInsight can now produce audit-ready documentation with full traceability instantly. This organized, structured approach leaves auditors impressed and confident in their compliance.

- **Improved Client Satisfaction:** Faster turnarounds and greater assurance of quality documentation have led to increased trust and stronger, more successful business relationships.