

**Jama connect**

Manage Risk, Enhance Safety, and Expedite Development and Launch of Combination Products with Jama Connect®

Combination devices or products such as inhalers or injectables that administer medications lie at the intersection of pharmaceuticals, biologics, engineering, and medical science. As a result, their development is a complex and interdisciplinary endeavor that often involves integrating a hierarchy of requirements with diverse regulatory demands across markets.

Jama Connect® is a powerful requirements management tool that streamlines the process of developing combination products that are safe, effective, and compliant.

Key Benefits

Streamline Compliance

Combination products must adhere to stringent regulatory and quality standards, such as ISO 13485, ISO 14971, ISO 11608, and FDA requirements. Jama Connect streamlines the certification process and minimizes the risk of non-compliance by providing tools for document control, verification, and validation, and the creation of audit trails essential for providing compliance.

Simplify Complex Traceability

The efficacy, quality, and safety of combination products depends on harmonizing a complex hierarchy of requirements including user needs, system requirements, risk evaluations, subsystems, verifications, and validations. Live Traceability™ in Jama Connect simplifies the process by enabling development teams to maintain proper traceability throughout the product development lifecycle to ensure that every design element from software to physical hardware meets the specified requirements.

Jama Connect Adheres to the Following Protocols

Built on Jama Software's Secure and Scalable Cloud Platform



Suitably validated by TÜV SÜD for safety-related development per IEC 62304



Jama Connect is SOC2 Type 2 certified in both the server and application



Ensures strong privacy management practices

TLS

Data transferred is secured and encrypted

Facilitate Reuse

Combination product development often involves adapting product designs to specific requirements of diverse regulations across markets. Jama Connect significantly reduces redundancy, minimizes errors, and speeds up development cycles by facilitating the efficient reuse of requirements, hazards, risk assessments, and verification testing across projects; tracking the evolution of variants; assessing the impact of change across all systems; and ensuring compliance with international standards.

Integrate Risk Management

The safety of patients relying on combination products to administer accurate doses of medication is paramount. Jama Connect integrates risk management with the design process by allowing development teams to maintain a comprehensive library of known and potential hazards, and define, document, and classify hazards and their corresponding risk assessments.

Foster Efficient Reviews

Meeting deadlines for product development, approvals, and launches requires timely reviews to uncover issues, assess design tradeoffs, and ensure alignment with requirements. Jama Connect fosters efficient communication and reduces the time required for reviews by providing an intuitive, easy to use collaborative platform for stakeholders to provide feedback, track changes, and sign off on design decisions.

By leveraging Jama Connect, combination product development teams can significantly improve their efficiency, reduce errors, enhance safety, and expedite development while maintaining the highest standards of quality and regulatory compliance.



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.