![Jama Software logo]

Accelerate Innovation in Medical Device Development, While Adhering to Industry Regulations

Bringing a medical device to market requires navigating a sea of complex and always-changing regulations, not to mention bearing significant costs along the way. But with the right requirements management solution, you can accelerate the development of cost-effective products that also comply with all applicable safety and quality standards.

Overcoming the Biggest Challenges in Medical Device Development

A device recall can cost $600 million, while the indirect costs of lost revenue and diminished market cap are even higher, at **$1-3 billion per company.**

Those costs are especially significant considering the price tag of product development—**$75 million in FDA compliance** alone, and an average timeline of three to seven years.

Connected devices are a major opportunity for device manufacturers, **as 40% of the IoT is healthcare-related**, but one-third of IT leaders cite security as a top concern.

How Jama Connect for Medical Device Development Can Help

Jama Connect provides a single platform for **managing device requirements, risks and design controls**—a much more efficient alternative to legacy systems and document-based workflows.

Our platform is tightly aligned with regulatory standards such as ISO 13485:2016, ISO 14971:2019, FDA 21 CFR 820.30 , ISO 14971:2019 and FDA 21 CFR part 11.

Tight alignment to industry regulations results in a **straightforward process for regulatory submissions and audit preparations**, accelerating time to market.

Live traceability makes it easy to **track potentially problematic changes**, while industry-specific export templates and design reports help streamline the device development process.

Unlocking a Better Customer Experience

Ease of implementation through out-of-the-box templates and a medical device framework, for shortened onboarding that gets users up and running quickly.

Jama Software customers have been able to **reduce planning time as much as 80%**, thanks to consolidated feedback replacing emails and versioned documents.

This transition from highly manual processes to real-time collaboration has **saved some companies hundreds of thousands of dollars per device development project.**

Better-quality products get out the door faster. By understanding the impact of change, capturing decisions and feedback and reusing existing IP, Jama Software **reduces medical device development time by an average of 130 days per project.**

Jama Software reduces rework, which accounts for approximately 30-50% of a given project and arises from issues such as requirements errors. Improving the ability to track requirements from design through verification and validation ensures teams build the right medical devices with the lowest possible overall lifecycle costs.

Learn more about **Jama Connect for Medical Device by downloading our eBook**, Buyers Guide: Selecting the Right Medical Device Development Platform.

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