jama connect®
Medical Device Risk Management Package

Medical device and life science companies need to incorporate integrated risk management and risk-based thinking into their product development process. The Jama Connect® for Medical Device and Life Sciences Development solution helps teams reduce the effort required to achieve regulatory compliance throughout the development process. With this solution, teams can manage design controls for device requirements and related risks, simplify regulatory submissions and audit preparations, while accelerating time to market. This solution comes fully aligned to industry regulations such as:

- ISO 13485: 2016, 14971:2019
- 21 CFR 820.30
- IEC: 60812, 62304
- EU MDR and IVDR

The Jama Connect Medical Device Risk Management Package supplements out-of-the-box functionality of Jama Connect seamlessly through use of Jama Connect Interchange™ — helping customers manage advanced risk activities to support their desired risk management strategy.

With this package, customers benefit from a fully integrated risk management process in Jama Connect and support for industry-leading risk management best practices.

Jama Connect's Medical Device Risk Management Package supplements out-of-the-box functionality to enable you to:

- Provide risk management solutions with advanced features such as information flow, complex risk calculations, and logic capabilities
- Implement specific risk management use cases such as hierarchical FMEA or enterprise risk portfolio management

Recommended Services (included with a subscription to a Jama Software® Success Program):

- Risk Management Consultation
- Reuse Consultation
- Custom Risk/FMEA Report
- Inheritance of Fields for Information Flow
- Advanced Risk Calculations and Lookup Matrices
- Hierarchical FMEA Approach
- Platform Risk Management on Single Product Family

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

To learn more, visit us at jamasoftware.com