

Medical Device eQMS

The Challenge: Traditional Quality Management Is Holding You Back

Medical device companies face rigorous regulatory requirements for CE marking in the EU or FDA authorisation in the US. Traditional quality management systems involve:

- Overwhelming paperwork and documentation
- Siloed information across multiple platforms
- Inefficient approval processes that delay product launches
- Limited collaboration between quality and development teams
- Higher costs from maintaining multiple systems

The Solution: A Fully Digital QMS on Platforms You Already Use

As a modern software development team, it is likely you are already using Atlassian's suite of products. Our electronic Quality Management System (eQMS) leverages the power of Atlassian's Confluence and Jira platforms to create a seamless, compliant, and efficient quality management solution specifically designed for medical device companies.

Our Services Include:

Assessment: We evaluate your current processes and workflows through workshops and gap analyses.

Configuration: We customize Confluence and Jira with the necessary apps and templates.

Validation: We ensure your system meets all regulatory requirements as per ISO13485 Section 4.1.6.

Training: We provide comprehensive training for your team.

Support: We offer ongoing support to ensure your continued success.

Ready to Transform Your Medical Device QMS?

Contact us today to schedule a demonstration and see how our Confluence and Jira-based eQMS can help you achieve compliance while accelerating your medical device development.

