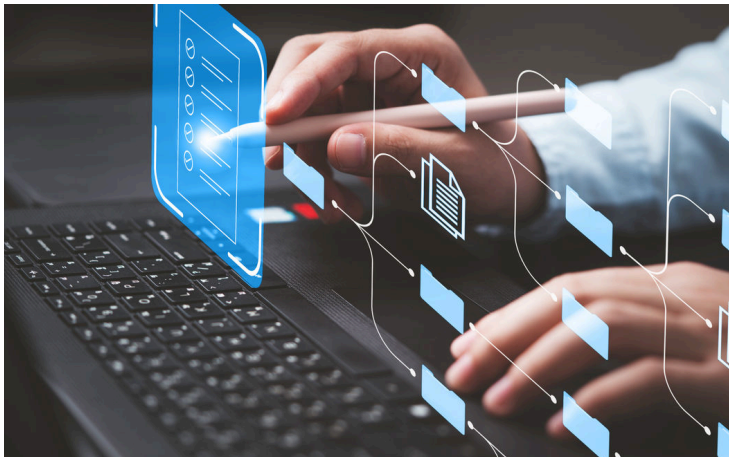
Medical Device Quality Management System

The medical device industry considers quality to be non-negotiable. To get innovative medical device software to market and ensure they are safe and effective, medical device manufacturers must have an effective quality management system (QMS). Compliance with legislative requirements, such as **FDA's 21 CFR Part 820**, **ISO 13485** and **EU MDR**, is mandatory for gaining approval from regulatory authorities in the target market.

Navigating the complexities of regulations and standards can be challenging for medical device software companies. It can be difficult to create and maintain a QMS that is compliant with all of the necessary legislative and regulatory requirements across different markets, like the EU and the US. Without a strong QMS, companies risk non-compliance, delays in entering markets, legal issues, and a damaged reputation.

At wega, our expert medical devices consultants can help you develop, implement, and maintain a QMS that meets the highest quality management standards and helps you achieve your business goals. We offer comprehensive support throughout the entire product lifecycle, from initial concept to post-market surveillance.



Our Services Include:

QMS Development and Implementation: We can develop and implement a QMS tailored to your organization's specific needs and compliance with standards. We also offer an elegant eQMS solution for medical device software start-ups.

QMS Maintenance and Optimization: We help you maintain your QMS through continuous monitoring, and management reviews.

Internal and Supplier Audits: Our services include conducting internal and supplier audits.

Training: We provide training and education to embed quality at all levels of your organization.

Gap Assessments and Remediation: We can conduct quality management system gap assessments to identify areas for improvement and assist with remediation efforts.

Post-Launch Support: Our support extends beyond product launch to include services like complaint management and post-market surveillance.

Technical Documentation: We can provide guidance and support for creating and updating technical documentation and design dossiers for market access.

Risk Management: We offer services to help you set up and maintain a product risk management process in accordance with ISO 14971.

wega Informatik AG
St. Alban-Graben 3
4051 Basel

info@wega-it.com
+41 (61) 270 87 87

360° Services in Life Science, Pharma, and Healthcare Informatics