Quality Management Systems (QMS) According to EN ISO 13485

Your partner for implementing, optimizing, and certifying quality management systems

EN ISO 13485 is the international standard for quality management systems in the medical device sector. It defines the requirements manufacturers and suppliers must meet to ensure the safety and effectiveness of their products. Implementing an EN ISO 13485-compliant QMS is a crucial step in meeting regulatory requirements and ensuring market access.

Our experienced team supports you in developing, implementing, and maintaining a robust and audit-ready QMS.

Our expertise

- Extensive experience in implementing QMS for companies of all sizes
- Up-to-date knowledge of global regulatory requirements
- Interdisciplinary teams of engineers and natural scientists
- Proven track record in supporting numerous certifications

Our services

- Introduction and optimization of QMS according to EN ISO 13485
- Gap analyses to identify improvement opportunities
- Preparation of processes and standard operating procedures (SOPs)
- Preparation for certifications and external audits
- Support during internal audits and management reviews
- Employee training and workshops

Your benefits

- Ensuring compliance with regulatory requirements
- Optimization of internal processes and efficiency
- Systematic processes improve product safety, traceability and risk management
- Reduction of risks and errors through structured approaches

valicare
GMP Compliance Services & Solutions

Contact us if you are looking to implement a quality management system according to ISO 13485. Together, we will find the best solution for your company!

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