Risk Management According to EN ISO 14971

Your partner for effective and compliant risk management in the medical device sector

EN ISO 14971 is the global standard for risk management of medical devices. It mandates systematic identification, analysis, evaluation, and monitoring of risks throughout the entire lifecycle of a medical device. Robust risk management is not only a regulatory requirement but also essential for ensuring patient safety and building trust among market participants.

Our team of experts helps you establish and implement an effective and audit-ready risk management system.

Our expertise

- In-depth knowledge of EN ISO 14971 and related standards
- Hands-on experience with risk management methodologies
- Interdisciplinary teams of engineers and scientists

Our services

- Implementation of a risk management system according to EN ISO 14971
- Risk identification and assessment (e.g., FMEA, fault tree analysis)
- Preparation and review of risk management files
- Support for integrating risk management into the product lifecycle
- Training and workshops on EN ISO 14971

Your benefits

- Reduction of risks through proactive risk management
- Improved product safety and patient satisfaction
- Regulatory compliance
- Time and cost savings through structured processes

valicare
GMP Compliance Services & Solutions

Contact us if you need support with risk management according to EN ISO 14971. We guide you toward a safe and compliant product!

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