Risk management according to ISO 14971:2019 / EN ISO 14971.

How medical device manufacturers realize, apply and document risk management according to ISO 14971 / EN ISO 14971.

Seminar	Zurzeit keine Termine	Teilnahmebescheinigung
Präsenz	8 Unterrichtseinheiten	

Seminarnummer: 09396

Stand: 03.05.2026. Alle aktuellen Informationen finden Sie unter https://akademie.tuv.com/s/09396

All medical device manufacturers must implement and document a risk management process. Learn how to implement the requirements of ISO 14971:2019 / EN ISO 14971 over all life cycles for your medical device and take into account the changes of the third edition from 2019. You will learn how to perform a risk analysis, correctly assess the risks and successfully minimize them.

Nutzen

- You will get an overview of the current regulatory requirements for risk minimization that manufacturers of medical devices must comply with.
- You will learn about the contents and requirements of ISO 14971:2019 / EN ISO 14971 as well as the purpose and procedure of a risk analysis.
- You will be enabled to systematically implement the risk management process in your company.
- You will deepen your knowledge with practical examples.

Zielgruppe

The seminar is for regulatory affairs specialists, quality management specialists as well as employees from the areas of quality and product management, design and development from companies in the medical device industry.

Abschluss

Teilnahmebescheinigung

Inhalte des Seminars

- Regulatory requirements to minimize the risks associated with medical devices
- Requirements of European regulations (MDR, IvDR)
- Risk management EN ISO 14971 vs. quality management EN ISO 13485 - Risk-based approach to products and QMS processes
- ISO 14971:2007 vs. ISO 14971:2019
  - new and amended terms and definitions
  - Structure and set-up
  - Risks, hazards and their evaluation
- Procedure and methods for risk analysis (e.g. fault tree analysis, FMEA)
- Risk management versus risk analysis
- Holistic risk assessment over the entire life cycle and connection with post market surveillance
- Documentation in risk management

Wichtige Hinweise

- The seminar contents take into account the current status of regulations/harmonization
- the handout is in English

Terminübersicht und Buchung

Buchen Sie Ihren Wunschtermin jetzt direkt online unter https://akademie.tuv.com/s/09396 und profitieren Sie von diesen Vorteilen:

- Schneller Buchungsvorgang
- Persönliches Kundenkonto
- Gleichzeitige Buchung für mehrere Teilnehmer:innen

Alternativ können Sie das Bestellformular verwenden, um via Fax oder E-Mail zu bestellen.