Quality management system according to EN ISO 13485.

Understand, interpret and implement requirements of EN ISO 13485:2016 for the medical device industry.

Seminar | Zurzeit keine Termine | Teilnahmebescheinigung

Präsenz | 8 Unterrichtseinheiten

Seminarnummer: 09397

Stand: 21.02.2026. Alle aktuellen Informationen finden Sie unter https://akademie.tuv.com/s/09397

The EN ISO 13485 is the basis for QM systems in the medical device industry. EN ISO 13485:2016 defines new requirements for medical device manufacturers and specifies the requirements of the predecessor standard. Get to know the structure and contents of EN ISO 13485:2016 and learn how to set up or adapt your QM system accordingly.

Nutzen

- You will learn about the structure, contents and requirements of EN ISO 13485:2016/AC:2016 as well as the main differences to the previous version EN ISO 13485:2012+AC:2012.
- You know how to introduce a QM system based on EN ISO 13485: 2016/AC:2016 or how to adapt your own quality management system to the new requirements.
- You benefit from concrete practical examples that make it easier for you to implement or adapt your system.

Zielgruppe

The seminar is suitable for employees who are or will be responsible for the implementation of EN ISO 13485 in medical device companies.

Abschluss

Teilnahmebescheinigung

certificate of attendance

Inhalte des Seminars

- Structure, (new) requirements of EN ISO 13485:2016/AC:2016
  - EN ISO 13485:2016/AC:2016 and the specific national, regional or international regulatory requirements for medical device manufacturers
  - Integration of risk management in the QM system or in the company processes including outsourced processes and the entire product life cycle
  - Selection and ongoing evaluation of suppliers
  - Documentation structure and evidence documents
  - Validation, verification, design transfer
  - dealing with complaints
  - Feedback and reporting
  - Major differences to EN ISO 13485:2012+AC:2012
- Audits and inspections according to EN ISO 13485:2016/AC:2016 by the notified body or competent authorities - EN ISO 13485:2016/AC:2016 versus MDR (Medical Device Regulation)
- ISO 13485 as the basis for the global Medical Device Single Audit Program (MDSAP)
- Tipps for implementing EN ISO 13485:2016/AC:2016 in your company

Wichtige Hinweise

- The seminar contents take into account the current status of regulations/harmonization
- The hand-out is English
- The training will be held in English

Terminübersicht und Buchung

Buchen Sie Ihren Wunschtermin jetzt direkt online unter https://akademie.tuv.com/s/09397 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.