

# Quality management system according to EN ISO 13485.

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

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|---------|------------------------|------------------------|
| Seminar | Zurzeit keine Termine  | Teilnahmebescheinigung |
| Präsenz | 8 Unterrichtseinheiten |                        |

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Seminarnummer: 09397

Stand: 20.08.2026. 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

## 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.