The new European Regulation on Medical Devices (MDR).

The Medical Device Regulation (MDR) in detail and its impact on market access for medical device manufacturers.

Seminar | Zurzeit keine Termine | Teilnahmebescheinigung

Präsenz | 8 Unterrichtseinheiten

Seminarnummer: 09523

Stand: 17.09.2025. Alle aktuellen Informationen finden Sie unter https://akademie.tuv.com/s/09523

With the Medical Device Regulation (MDR) the new EU Regulation on medical devices was published. Our seminar will inform you about the far-reaching effects that affect all medical devices and stakeholders in the medical device industry. We prepare you optimally for the new and changed requirements of the current regulatory framework.

Nutzen

- You are getting familiar with the new requirements of MDR, the main regulatory areas and the resulting responsibilities and obligations for medical device manufacturers and other stakeholders, such as contract manufacturers, packers and contract developers, distributors and representatives.
- You learn what has to be taken into account for a compliant implementation and can start the necessary actions in your company.

Zielgruppe

The seminar is for specialists and executives, employees from the medical device industry and their supply industry from the fields of quality assurance, regulatory affairs, development, production, product management as well as safety representatives for medical devices, EU representatives and employees from consulting and service companies in the medical device industry

Abschluss

Teilnahmebescheinigung

Certificate of attendance

Inhalte des Seminars

- Fundamentals, objectives, content and scope of the new Medical Device Regulation (MDR)
- Advanced and new essential safety and performance requirements
- Classification / reclassification of medical devices
- The main changes and changes with regard to:
  - Placing on the market, vigilance, market surveillance (post market surveillance)
  - Clinical evaluation and postmarket clinical follow-up
  - Technical documentation and its update
  - medical device registration; labeling and traceability (including EUDAMED, UDI)
  - Responsibilities and requirements of manufacturers, importers, EU representatives and other stakeholders
  - Responsible person for regulatory compliance
  - Scrutiny procedure
- Monitoring of manufacturers incl. supply chain by notified bodies and competent authorities
- Implementation timetable, transitional provisions and deadlines, impact on certification

Wichtige Hinweise

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

Terminübersicht und Buchung

Buchen Sie Ihren Wunschtermin jetzt direkt online unter https://akademie.tuv.com/s/09523 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.