

US MEDICAL DEVICE APPROVAL

In this training course you will gain insight into the specific requirements for launching medical devices in the US market.

The aim of the course is to familiarise you with the basic guidelines and requirements of the code of federal regulations, FDA and other relevant bodies. With tips and guidance to help you launch your product on the US market.

DURATION: 1 Day

LANGUAGE: English or German

COURSE CONTENT:

- 21 CFR Code of Federal Regulations
- Classification of medical devices
- Premarket approval: types, costs, timescale
- Premarket approval structure
- Predecessor products and equivalence
- US standards landscape and FDA guidance documents
- Software and FDA level of concern
- Quality management systems
- Unique device identifier
- FDA databases
- FDA audits
- FDA meeting format and structure
- FDA case for quality

TARGET AUDIENCE:

Regulatory, quality, design, development and manufacturing personnel

PREREQUISITES:

This course is suitable for delegates with no prior knowledge of the US approval process or can be customised for a more experienced audience.

FURTHER INFORMATION:

The training takes place either online or live. The duration of the training is 8 hours (including a 30 minute lunch break and 2 shorter breaks). On request we grant a discount for group bookings.

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TRAINER:
Verena Wieser

We are happy to work with your organisation to develop **customised and cost effective training** that meets your requirements in terms of date, timing and content.

**PLEASE CONTACT US FOR YOUR
BOOKING OR ENQUIRY:**

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