

## 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:** 1/2 Day

**PRICE:** € 350 / £ 325 per person

**LANGUAGE:** English or German

### COURSE CONTENT:

- 21 CFR Code of Federal Regulations
- Classification of medical devices
- Premarket approval: types, costs, timescale
- 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 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 and lasts 4 hours (including a short break). On request we grant a discount for group bookings.

**Your partner for functional safety  
and regulatory compliance.**

## US APPROVAL MEDICAL DEVICES



**TRAINER:**  
**Alastair Walker**

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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