Lorit Consultancy

# US APPROVAL
## MEDICAL DEVICES

## 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 familiarize 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 Documentation Level
- QMSR - Quality Management System Regulation
- Unique device identifier
- FDA databases
- FDA audits
- FDA meeting format and structure
- FDA case for quality
- Medical Device Reporting
- Cybersecurity
- Human Factors
- MDSAP

**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 customized 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.

We are happy to work with your organization to develop **customized 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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**Your partner for functional safety and regulatory compliance.**

**lorit-consultancy.com**

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