

ISO 13485 QUALITY MANAGEMENT SYSTEMS

The course content covers the basics of the ISO 13485 standard with working examples and team exercises based on our extensive industry knowledge. We will show you how to create your quality management manual and QM processes and how to define your quality policy and goals. The qualification and validation of software tools will be also addressed. In addition, the course includes a comparison of the requirements of the Medical Devices Regulation (MDR), IVDR, ISO 9001 and the American 21 CFR 820 with those of ISO 13485.

DURATION: 1 Day

LANGUAGE: English or German

COURSE CONTENT:

- Quality manual, quality policy and quality goals
- Responsibility of the management
- Resource management
- Product realization and service delivery
- Continuous improvement process
- Control of documents and records
- Qualification and validation of software tools
- Identification of regulatory requirements
- Post-market surveillance process
- Corrective and Preventive Action (CAPA)
- Connection to the Medical Devices Regulation (MDR), IVDR and ISO 9001
- Internal audits according to ISO 19011
- Medical Device Single Audit Program (MDSAP)

TARGET AUDIENCE:

Members of the senior management, quality managers, regulatory affairs staff, employees who are responsible for creating processes in their area of expertise.

PREREQUISITES:

This course is suitable for participants without prior knowledge of ISO 13485, or can be tailored for experienced participants.

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.

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

ISO 13485 QUALITY MANAGEMENT SYSTEMS: Requirements for regulatory purposes



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:

info@lorit-consultancy.com
+43 676 338 8884 or
+44 7708 360023