Lorit Consultancy

ISO 13485

QUALITY MANAGEMENT SYSTEMS:
Requirements for regulatory purposes

ISO 13485 QUALITY MANAGEMENT SYSTEMS – Requirements for regulatory purposes

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 de ine your quality policy and goals. The quali i-cation 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), ISO 9001 and the American 21 CFR 820 with those of ISO 13485.

DURATION: 1 Day

LANGUAGE: English or German

COURSE CONTENT:
- Quality management handbook, 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) 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 with several years of experience in software development or can be adapted to your previous knowledge.

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.

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

Your partner for functional safety and regulatory compliance.

lorit-consultancy.com

Drg-Nr. 901-00536-001