AWARENESS TRAINING · MEDICAL DEVICE QUALITY

ISO 13485:2016 Awareness

Self-paced online training (video) · 15 modules · about 115 min of video · about 3.5 hours in total · English, with captions

Build awareness of quality management for medical devices and the role of controlled processes, documentation and individual responsibilities.

WHO IT IS FOR

Employees, supervisors and managers in medical device design, manufacture, supply and service.

WHAT YOU WILL LEARN

- Explain what ISO 13485 is and how it supports regulatory compliance
- Describe the structure of the standard and how its clauses fit together
- Recognise why documentation, records and traceability matter for medical devices
- Understand how complaints and corrective and preventive action protect patients
- Describe your own part in device safety and quality

MODULES (15)

1. Welcome, and what ISO 13485 is
2. Why ISO 13485: patients, regulators and business
3. Quality: stated and implied needs
4. The structure of ISO 13485:2016
5. Your role, your device class and your scope
6. Processes, the risk-based approach and outsourcing
7. Quality policy and quality objectives
8. Documented information and the medical device file
9. Risk management across the product life cycle
10. People, infrastructure and work environment
11. Customer requirements and design and development
12. Purchasing, production, validation, traceability and release
13. Feedback, complaints, nonconforming product and corrective action
14. Preventive action, change, internal audit and management review
15. Making it work, and your part

PRICE

US$19 per learner

Per learner, by team size

1–10 learners	**US$19**
11–50 learners	**US$15**
51–200 learners	**US$13**

Excluding taxes.

DURATION

About 3.5 hours in total (114 minutes of video)

MODULES

15

FORMAT

Self-paced online training (video)

LANGUAGE

English, with captions

ACCESS

12 months

CERTIFICATE

Sterling Academy Certificate of Completion

Scan for the course page, prices and enrolment