PRACTITIONER TRAINING · MEDICAL DEVICE QUALITY

ISO 13485:2016 Implementation Training

Self-paced online training (video) · 26 modules · about 6 hours of video, plus practice exercises · about 13 hours in total · English, with captions

Put every ISO 13485:2016 requirement in place for your own devices and regulatory requirements, from the medical device file and design controls to sterile production, complaints and certification readiness.

WHO IT IS FOR

QMS leads building or rebuilding an ISO 13485 system, regulatory affairs specialists, design, production and supply-chain leads, and managers of medical device companies and contract manufacturers.

WHAT YOU WILL LEARN

- Document the QMS and its roles, and build the medical device file
- Control documents and records for the lifetime of the device
- Plan product realization with risk management, and control design and development
- Control purchasing, production, process validation, sterilization and traceability
- Handle feedback, complaints, reporting to regulatory authorities and nonconforming product
- Run CAPA, audits and management review, and plan for certification

MODULES (26)

1. Welcome: a QMS for medical devices
2. The language of the standard
3. How the standard is built
4. General requirements
5. The quality manual and the medica...
6. Control of documents and of records
7. Commitment, policy and objectives
8. Roles, representative and commun...
9. Management review: input and out...
10. Resources and human resources
11. Infrastructure and work environment
12. Planning realization and risk mana...
13. Customer-related processes
14. Design and development: plan, inp...
15. Design and development: verify to f...
16. Purchasing: suppliers and checks
17. Production control and sterile devi...
18. Process validation and sterilisation
19. Identification and traceability
20. Monitoring and measuring equipm...
21. Feedback, complaints and reporting
22. Internal audit and monitoring
23. Nonconforming product and data
24. Corrective and preventive action
25. The procedures and records you ne...
26. Your road map and certification rea...

PRICE

US$99 per learner

Per learner, by team size

1–10 learners	**US$99**
11–50 learners	**US$79**
51–200 learners	**US$69**

Excluding taxes.

DURATION

About 13 hours in total (6 hours of video)

MODULES

26

FORMAT

Self-paced online training (video)

LANGUAGE

English, with captions

ACCESS

12 months

CERTIFICATE

Sterling Academy Certificate of Competence

Scan for the course page, prices and enrolment