PRACTITIONER TRAINING · AUDITING

ISO 13485:2016 Internal Auditor Training

Self-paced online training (video) · 26 modules · about 6 hours of video · about 8.5 hours in total · English, with captions

Plan and carry out internal audits of a medical device quality management system against ISO 13485:2016, clause by clause, following ISO 19011:2026 guidance, from checklists to nonconformities and follow-up.

WHO IT IS FOR

Quality and regulatory affairs staff, design, production and supply-chain team members, CAPA and complaint owners, and anyone appointed to carry out internal audits of an ISO 13485 quality management system.

WHAT YOU WILL LEARN

- Explain what ISO 13485:2016 requires of internal audits and the audit programme
- Plan a risk-based audit and prepare checklists from ISO 13485 and your regulatory requirements
- Audit each clause, from documentation and the medical device file to CAPA
- Sample design, production, validation and complaint records to gather objective evidence
- Write clear nonconformities that state the requirement, the evidence and what was found
- Report audit results and follow up corrections and corrective actions

MODULES (26)

1. Welcome: why device QMS internal...
2. The standard through an auditor's...
3. The internal auditor and ISO 1901...
4. General requirements: roles, proce...
5. Documentation and the medical de...
6. Control of documents and records
7. Commitment, policy and quality ob...
8. Roles, communication and manage...
9. Resources and competence
10. Infrastructure and the work enviro...
11. Planning, risk and customer proces...
12. Design and development: planning...
13. Verification, validation, transfer an...
14. Purchasing and supplier controls
15. Production, installation, servicing,...
16. Process validation and sterilisation
17. Identification and traceability
18. Feedback, complaints and reporting
19. Measuring equipment, processes,...
20. Nonconforming product and analys...
21. Corrective and preventive action
22. Planning and preparing the audit
23. Conducting the audit: opening and...
24. Sampling, evidence and audit trails
25. Findings, the closing meeting and t...
26. Follow-up, a practice audit, the exam

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 8.5 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 Completion

Scan for the course page, prices and enrolment