PRACTITIONER TRAINING · MEDICAL DEVICE QUALITY

MDSAP: Medical Device Single Audit Program Training

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 5.5 hours in total · English, with captions

Prepare your medical device quality system for a Medical Device Single Audit Program audit: the audit approach, its seven processes, the five regulators' added requirements, nonconformity grading and the audit cycle.

WHO IT IS FOR

Quality and regulatory affairs managers of medical device manufacturers selling in the United States, Canada, Australia, Brazil or Japan, QMS leads preparing for a first MDSAP audit, internal auditors of device quality systems and consultants supporting MDSAP readiness.

WHAT YOU WILL LEARN

- Explain how MDSAP works, who takes part and how each regulator uses the audit
- Follow the MDSAP audit approach, its sequence, processes, tasks and linkages
- Map ISO 13485:2016 and each jurisdiction's added requirements to your quality system
- Prepare records for adverse event reporting, advisory notices and marketing authorisation
- Grade nonconformities on the MDSAP five-level scale and respond within the timelines
- Build an MDSAP readiness plan and a gap assessment for your organisation

MODULES (13)

1. Welcome: why MDSAP matters
2. MDSAP at a glance: the regulators and the audit
3. The audit approach and the audit cycle
4. Process 1: Management
5. Process 2: Authorisation and registration
6. Process 3: Measurement, analysis and improvement
7. Complaints, adverse events and advisory notices
8. Process 5: Design and development
9. Process 6, part 1: validation, sterilisation
10. Process 6, part 2: records, traceability
11. Process 7: Purchasing
12. Grading nonconformities and the timeline
13. Putting it together: a mock MDSAP audit

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 5.5 hours in total (3 hours of video)

MODULES

13

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