PRACTITIONER TRAINING · MEDICAL DEVICE QUALITY

ISO 14971:2019 Medical Device Risk Management

Self-paced online training (video) · 33 modules · about 4 hours of video · about 6.5 hours in total · English, with captions

Build and maintain a medical device risk management file with ISO 14971:2019, from hazards and risk control to residual risk and post-production information.

WHO IT IS FOR

Risk, design, software, quality and regulatory teams of device manufacturers, contract manufacturers and distributors.

WHAT YOU WILL LEARN

- Tell a hazard, a hazardous situation and a harm apart, and trace the sequence of events between them
- Set up the policy for risk acceptability, the risk management plan and the risk management file
- Analyse intended use, reasonably foreseeable misuse, characteristics related to safety and hazards
- Choose risk control measures in the standard's order and verify their implementation and effectiveness
- Evaluate residual and overall residual risk, apply benefit-risk analysis correctly, and act on post-production information

MODULES (33)

1. Why device risk management matt...
2. Scope, life cycle and the manufact...
3. ISO 14971 and ISO 13485: one thr...
4. Hazard, hazardous situation, harm
5. Sequences of events
6. Risk: severity and probability
7. Top management and the policy
8. Risk acceptability criteria and the...
9. Competence and the risk manage...
10. The risk management file and trace...
11. Starting a risk analysis
12. Intended use and foreseeable mis...
13. Characteristics related to safety
14. Finding hazards: the Annex C chec...
15. Hazard-hunting techniques
16. Use error and usability
17. Software, data, security and IVDs
18. Risk estimation with data
19. Risk evaluation
20. The risk control option order
21. Risk control in practice
22. Implementing and verifying controls
23. Residual risk and risks from controls
24. Benefit-risk analysis
25. Completeness of risk control
26. The register, end to end
27. Overall residual risk and disclosure
28. Risk management review and report
29. Collecting production and market i...
30. Reviewing information and acting
31. Process risk on the shop floor
32. Suppliers, outsourcing and change
33. The auditor's view and your part

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 6.5 hours in total (4 hours of video)

MODULES

33

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