PRACTITIONER TRAINING · MEDICAL DEVICE QUALITY

Design Controls for Medical Devices

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 6 hours in total · English, with captions

Control medical device design and development from the plan to transfer, meeting ISO 13485:2016 and the FDA QMSR, with traceable inputs, outputs, reviews, verification, validation and design changes.

WHO IT IS FOR

R&D and design engineers, project managers, quality and regulatory affairs staff, software and systems engineers, and start-up founders developing medical devices for the United States, Europe and other regulated markets.

WHAT YOU WILL LEARN

- Plan design and development with stages, reviews and responsibilities
- Write design inputs that are complete, unambiguous and verifiable
- Produce design outputs and keep traceability from needs to tests
- Plan and run design verification and design validation, including usability
- Control design transfer and design changes
- Build a design and development file ready for audit and inspection

MODULES (13)

1. Welcome: why design controls matter
2. Design controls at a glance
3. The design and development plan
4. User needs and design inputs
5. Writing verifiable design inputs
6. Design outputs and acceptance criteria
7. Design reviews and traceability
8. Design verification and sample sizes
9. Design validation and usability
10. Design transfer and design changes
11. The design file and the medical device file
12. Software, connected devices and risk
13. Putting it together findings and 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 6 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