PRACTITIONER TRAINING · MEDICAL DEVICE QUALITY

Software as a Medical Device and IEC 62304 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

Develop and maintain medical device software to IEC 62304: when software is a medical device, risk categories and software safety classes, the life cycle processes, and what FDA and the EU expect.

WHO IT IS FOR

Software engineers, architects and testers, product managers, quality and regulatory affairs staff of medical device and digital health companies, and start-ups bringing software as a medical device to the US or EU markets.

WHAT YOU WILL LEARN

- Decide whether software qualifies as a medical device in the US and the EU
- Apply the IMDRF SaMD risk categories and IEC 62304 software safety classes
- Plan and run the IEC 62304 development process, from requirements to release
- Link software risk management to ISO 14971 and control software of unknown provenance
- Maintain released software with configuration management and problem resolution
- Prepare the software documentation FDA and EU notified bodies expect

MODULES (13)

1. Why software safety matters
2. When software is a medical device
3. Risk categories and classes
4. IEC 62304 at a glance
5. Software safety classes
6. Planning and requirements
7. Architecture, design and units
8. Integration, testing, release
9. Software risk management
10. SOUP, configuration, problems
11. Maintenance and cybersecurity
12. Changes and submissions
13. Putting it together

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