AWARENESS TRAINING · MEDICAL DEVICE QUALITY

Computer Software Assurance (CSA) Training (US FDA)

Self-paced online training (video) · English, with captions

Apply FDA's February 2026 Computer Software Assurance guidance to production and quality system software: intended use, high process risk, scripted and unscripted testing, vendor evidence, records and Part 11.

WHO IT IS FOR

Validation and quality engineers, QA and regulatory staff, IT and system owners, and managers at medical device manufacturers in the United States or exporting to it, who select, configure, test or approve software used in production or the quality management system.

WHAT YOU WILL LEARN

- Explain where the duty to validate production and quality system software comes from under the QMSR
- Decide whether a software feature, function or operation is used as part of production or the quality system
- Judge whether a feature poses a high process risk, as FDA's guidance describes it
- Choose assurance activities, from vendor evidence to scripted and unscripted testing
- Build a lean, complete record of assurance for each software feature
- Apply Part 11 and the guidance to cloud software, changes and periodic review

PLANNED OUTLINE

1. Why CSA
2. The duty to validate
3. Risk and assurance
4. Records and electronic records
5. CSA in practice

PRICE
coming soon

DURATION
coming soon

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