CEISO
TRAINING CENTER

REF. MQ10 - INTRA/INTER

QUALITY SYSTEM

Validation of Software Applications

COURSE DESCRIPTION

This course will allow you to acquire practical knowledge to validate software applications in accordance with the requirements of ISO 13485:2016.

N.B. This course does not cover the validation of software considered to constitute Medical Devices or of software incorporated into Medical Devices.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Understand applicable normative requirements
- Understand the software application validation methodology
- Define and manage validation documents
- Apply the concepts learned to case studies

TARGET TRAINEES

Manufacturers of Medical Devices and subcontractors

PREREQUISITES

Familiarity with the requirements applicable to quality management systems (ISO 13485)

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Examples tailored to the company's products
- Group exercises
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Introduction
2. Regulatory, normative and industrial context
3. Software application validation principles
   a. Key principles
   b. Lifecycle approach
   c. Risk management
4. Software application validation activities
   a. General information
   b. Validation process
   c. Documentation
5. Validation of a software application - implementation
   a. Validation plan, risk management
   b. Documentation
6. Summary/Q&A
7. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program *(success criteria >= 75%).*

Do you have a question? Contact us!
Email: formation@ceiso.fr
Tel.: +33 6 42 58 94 52