



# Quality Management System for Medical Devices

## COURSE DESCRIPTION

CE-marking requires the implementation of a Quality organization. European standard EN ISO 13485 sets out the requirements for the Quality Management System to enable an entity to demonstrate its ability to regularly supply Medical Devices that comply with customer requirements and applicable regulations.

## DURATION

1 day/7 hours



IN-PERSON



VIRTUAL CLASSROOM

## OBJECTIVES

- Become familiar with the terms and vocabulary
- Analyze and understand EN ISO 13485 requirements
- Identify the ties between the regulations and EN ISO 13485

## TARGET TRAINEES

- Medical Device manufacturers
- Operators in an ISO 13485 environment
- Quality Managers
- Quality Engineers

## PREREQUISITES

- Familiarity with basic Quality Management principles
- Familiarity with the Medical Device sector

## TRAINING RESOURCES

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

## COURSE CONTENT

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

1. Introduction
  - a. A brief history
  - b. Normative and regulatory framework
  - c. Scope
  - d. Exclusion - non-applicability
  - e. A few definitions
2. Quality Management principles and concepts
  - a. What is a process approach?
  - b. What is continuous improvement?
  - c. Quality Management principles
3. Analysis of ISO 13485:2016 requirements
  - a. Chapter 4: Quality Management System
  - b. Chapter 5: Management responsibility
  - c. Chapter 6: Resource management
  - d. Chapter 7: Product realization
  - e. Chapter 8: Measurement, analysis and improvement
4. Summary/Q&A
5. 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*  $\geq 75\%$ ).



**Do you have a question?** Contact us!

Email: [formation@ceiso.fr](mailto:formation@ceiso.fr)

Tel.: +33 6 42 58 94 52