



Clinical Investigations of Medical Devices

REF. CL05 - INTRA/INTER

CLINICAL

COURSE DESCRIPTION

The demonstration of a Medical Device's compliance with the General Safety and Performance Requirements (GSPR) may include a clinical investigation according to Regulation (EU) 2017/745. The goal of this clinical investigation is to collect safety and performance data specific to the device. It must be planned, designed and conducted according to the regulatory and ethical recommendations in effect.

DURATION

1 day/7 hours



IN-PERSON



VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with the terms and vocabulary
- Understand the regulatory ((EU) 2017/745), legal and ethical requirements for clinical investigations
- Become familiar with the essential documents and steps to take to conduct an investigation

TARGET TRAINEES

- Medical Device manufacturers
- Medical Device development or market operators

PREREQUISITES

- No prior knowledge required

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Work is based on applicable regulations and standards
- Distribution of the information presented
- Quizzes

COURSE CONTENT

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

1. Clinical investigations: context and definitions
 - a. Introduction to clinical research
 - b. Regulatory and legal context
 - c. The different types of studies
 - d. Roles and responsibilities
 - e. Investigation design
2. Essential documents and their use
 - a. Essential study documents
 - b. Submission of the investigation
 - c. Major study stages
 - d. Conduct of the investigation
 - e. Good Clinical Practices and Vigilance
3. Summary/Q&A
4. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on each individual's acquisition of knowledge via quizzes during and at the end of the program (*success criteria* $\geq 80\%$).



Do you have a question? Contact us!

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