CEISO
TRAINING CENTER

REF. CL06 - INTRA/INTER

CLINICAL

Clinical Investigations and Good Clinical Practices according to ISO 14155

COURSE DESCRIPTION

The demonstration of a Medical Device's compliance with the General Safety and Performance Requirements may include a clinical investigation. The goal of this clinical investigation is to collect safety and performance data specific to the device. A clinical investigation must be conducted in accordance with Good Clinical Practices, which ensure ethical and scientific quality.

DURATION
1.5 days/10.5 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Identify the regulatory stages and obligations for an investigation
- Understand the requirements for a clinical investigation in order to comply with Regulation (EU) 2017/745, the legal obligations in effect, and Good Clinical Practices according to ISO 14155:2020

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 investigation: context and definitions
   a. Terms and definitions
   b. Regulatory (Regulation (EU) 2017/745) and legal framework
   c. The different types of studies
   d. The different parties and their responsibilities
   e. Investigation design
2. Clinical investigation: essential documents
   a. Study documents
   b. Submission and evaluation of the investigation
   c. Major study stages
3. GCP: context and application
   a. ISO 14155
   b. Ethical considerations
   c. Quality Assurance and Control
4. Summary/Q&A
5. 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 >= 80%).*

Do you have a question? Contact us!
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