CEISO
TRAINING CENTER

Clinical Evaluation and Literature Review Methodology

REF. CL03 - INTRA/INTER

CLINICAL

COURSE DESCRIPTION

The demonstration of compliance with the General Safety and Performance Requirements (GSPR) must include a clinical evaluation. This clinical evaluation consists in the planning and conduct of a critical review of the clinical data for the Medical Device under evaluation. This data is analyzed to evaluate the safety, performance and clinical benefits of the product considering the state of the art documented and based on a methodical literature review.

DURATION
1.5 days/10.5 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with the regulatory requirements for clinical evaluations
- Identify the clinical evaluation stages
- Learn the basics to draft the report
- Know how to search data by following a literature review protocol

TARGET TRAINEES

- Medical Device manufacturers
- Medical Device development or market operators

PREREQUISITE

- No prior knowledge required

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Work is based on applicable regulations and the MEDDEV 2.7/1 guidelines
- Quizzes

COURSE CONTENT

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

1. Clinical evaluation: context and definitions
   a. Terms and definitions
   b. Regulation (EU) 2017/745, MEDDEV 2.7/1 revision 4 guidelines
   c. Clinical evaluation stages
   d. Clinical benefits and claims
   e. State of the art
2. What data? How to analyze it?
   a. Equivalence: how and when?
   b. Performance data
   c. Safety data
   d. Compliance with the requirements: conclusion
3. Literature review
   a. Use databases
   b. Define search criteria
   c. Define and follow a search method
   d. Practical examples
4. Summary/Q&A
5. Course evaluation and conclusion

EVALUATION METHODS

Training 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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