



Systematic Literature Review Methodology

REF. CL01 - INTRA/INTER

CLINICAL

COURSE DESCRIPTION

The demonstration of a product's compliance with the general requirements must include a review of the literature. This review, which is part of the preparation of a clinical investigation or evaluation, must be methodical and documented.

DURATION

1 day/7 hours



IN-PERSON



VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with the terms and vocabulary
- Understand the regulation's requirements in terms of clinical evaluations
- Learn the basics for the conduct of a literature review (state of the art and clinical data specific to MDs)

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
- Examples tailored to the company's products
- 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
 - c. MEDDEV 2.7/1 revision 4 guidelines
 - d. Become familiar with the different stages of a clinical evaluation
 - e. Identify clinical benefits and claims
 - f. Identify the points to be presented in the state of the art
2. Literature review: What data? How to analyze it?
 - a. Use databases and search engines
 - b. Determine selection criteria for references
 - c. Define a method to select references
 - d. Assess the reliability of the evidence presented in the scientific articles selected
 - e. Practical examples
3. Summary/Q&A
4. 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* $\geq 80\%$).



Do you have a question? Contact us!

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