



# Clinical Evaluation of a Medical Device

REF. CL02 - INTRA/INTER

CLINICAL

## COURSE DESCRIPTION

The demonstration of a Medical Device's 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 (MD) under evaluation and the analysis of this data to assess the safety, performance and clinical benefits of the product considering the state of the art.

## 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
- Become familiar with the basics to draft a clinical evaluation report

## 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
  1. Terms and definitions
  2. Regulation (EU) 2017/745 requirements
  3. MEDDEV 2.7/1 revision 4 guidelines
  4. Become familiar with the different stages of a clinical evaluation
  5. Identify clinical benefits and claims
2. The different sections of a CER
  1. Claiming equivalence: when and how?
  2. Sources of performance data
  3. Sources of safety data
  4. Data compilation and analysis
  5. Compliance with the general requirements: conclusion
  6. Practical examples
3. Summary/Q&A
4. 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*  $\geq 80\%$ ).



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

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