



# Clinical Performance Study for an *In Vitro* Diagnostic Medical Device

## COURSE DESCRIPTION

The demonstration of the product's compliance with the general requirements of Regulation (EU) 2017/746 may include a clinical performance study, which is intended to produce data to clinically establish or confirm the analytical performance of a device. This course's objective is to identify the regulatory obligations relative to the implementation and conduct of a clinical performance study.

### DURATION

1 day/7 hours



**IN-PERSON**



**VIRTUAL CLASSROOM**

## OBJECTIVES

- Become familiar with the terms and vocabulary
- Understand the requirements of Regulation (EU) 2017/746 and ISO 20916 regarding good practices for clinical performance studies
- Identify the essential documents required
- Become familiar with the basics to design and conduct a clinical performance study

## TARGET TRAINEES

- Manufacturers of *In Vitro* Diagnostic Medical Devices (IVDMD)
- IVDMD 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
- Reference to Regulation (EU) 2017/746 (IVDR) and ISO 20916
- Distribution of the texts presented
- Quizzes

## COURSE CONTENT

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

1. Context and definitions
  - a. Terms and definitions
  - b. Regulatory and legal requirements
  - c. Ethical considerations
2. When should a clinical performance study be conducted?
3. Study design
  - a. The different types of studies
  - b. Design parameters
  - c. The essential documents required
4. Study conduct
  - a. Submission and regulatory evaluation of the study
  - b. Conditions to be met to conduct the study
  - c. Study conduct
  - d. Monitoring quality
  - e. Clinical performance study report
  - f. Practical examples
5. Summary/Q&A
6. 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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