



# Clinical Performance Evaluation of an *In Vitro* Diagnostic Medical Device

## COURSE DESCRIPTION

The demonstration of the compliance of an *In Vitro* Diagnostic Medical Device (IVDMD) with the general requirements of Regulation (EU) 2017/746 may include a performance evaluation intended to establish or verify the scientific validity and clinical performance of a device.

## 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 in terms of the performance evaluation
- Become familiar with the basics to draft a performance evaluation report

## TARGET TRAINEES

- Manufacturers of *In Vitro* Diagnostic Medical Devices
- IVDMD development or market operators

## PREREQUISITES

- Familiarity with the Medical Device regulation

## TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Examples tailored to the company's products
- 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. Regulation (EU) 2017/746 requirements
2. Evaluation of the performance of an IVDMD
  - a. The different characteristics
  - b. Documents to be prepared
3. Performance evaluation report
  - a. Composition
  - b. Goals targeted
  - c. The different sections of the Performance Evaluation Report: What data? How to analyze it?
4. Literature review methodology
  - a. The different sources of information
  - b. Selection and critical evaluation of the literature's data
  - c. Data analysis to establish the state of the art or the clinical performance of an IVDMD
5. Summary/Q&A
6. 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*  $\geq 80\%$ ).



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

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