



# Post-Market Surveillance & Vigilance

Regulation (EU) 2017/745

NEW

REF. E-MDR-MOD-10 – E-LEARNING

EUROPEAN REGULATIONS

## COURSE DESCRIPTION

The Post-Market Surveillance & Vigilance module describes the purpose of post-market surveillance and the procedures to implement based on the type of data collected.

### DURATION

30 minutes, including a 20-minute lesson and 10 minutes of quizzes



**E-LEARNING**

### TECHNICAL PREREQUISITES

Computer and internet connection

## METHODS USED

The module is composed of a lesson in the form of an **interactive video with voice-off** and **learning activities**. The module can be **accessed 24/7**. Reminders are sent to monitor knowledge acquisition and avoid a break in the learning curve.

## TARGET TRAINEES

All individuals involved in the MD sector

## PREREQUISITES

Knowledge of the Regulation's main definitions and general principles, more particularly those regarding product classification and the principles to demonstrate and monitor clinical benefits (N.B. covered in the Overview, MD Classification and Clinical Evaluation modules)

## ACCESS

The CEISO ACADEMY platform can be accessed for a period of two months within two business days at most of approval of your order.

## ADDITIONAL BENEFITS

Summary presentation of the regulation

Support materials **designed by experienced consultants-trainers**

**Interactive lesson**

**Short modules** that can be accessed as often as required and **autonomously**

As an option, you may select **Q&A sessions** with one of our consultants-trainers

## EDUCATIONAL GOALS

- Understand the need for post-market surveillance
- Become familiar with the procedures to apply based on the type of data collected

## COURSE CONTENT

### Assistance with navigation/Module objectives/Presentation of the course content

1. Post-market surveillance (PMS)
2. Claim processing
3. Vigilance
4. Processing other relevant information
5. Post-market clinical follow-up (PMCF)

## EVALUATION METHODS

Course evaluation quiz  
Satisfaction survey  
Attendance certificate

This training is assessed based on each individual's acquisition of knowledge via a quiz at the end of the program (*success criteria*  $\geq 80\%$ ). If trainees pass the quiz, they receive their training certificate, as well as the corrected quiz, by email.



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

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