



# Quality Management System

## Regulation (EU) 2017/745

REF. E-MDR-MOD-11 – E-LEARNING

EUROPEAN REGULATIONS

### COURSE DESCRIPTION

The Quality Management System module presents the manufacturer's obligations regarding the Quality Management System and how it is assessed.

### DURATION

23 minutes, including a 15-minute lesson and 8 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

Familiarity with the Regulation's main definitions and general principles, more particularly market authorization procedures, conformity assessments and post-market surveillance (N.B. covered in the Overview, Market Authorization, Conformity Assessment and Post-Market Surveillance and Vigilance 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

- Become familiar with the manufacturer's obligations regarding the quality management system
- Understand how this QMS is assessed by a notified body

### COURSE CONTENT

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

1. Requirements applicable to the Quality Management System
2. Quality Management System evaluation
3. Quality Management System evaluation request

### 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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