

# Package for RESEARCH & DEVELOPMENT

## Regulation (EU) 2017/745

NEW

### COURSE DESCRIPTION

The RESEARCH & DEVELOPMENT package is composed of 6 modules and has been designed specifically to present, in an interactive format, the main obligations of the R&D Department to ensure compliance with Regulation (EU) 2017/745.

### DURATION

185 minutes, including 120 minutes of lessons and 65 minutes of quizzes



### E-LEARNING

### TECHNICAL PREREQUISITES

Computer and internet connection

### METHODS USED

The modules are composed of lessons in the form of **interactive videos with voice-off** and **learning activities**. They 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, and more particularly the R&D Department

### EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on research and development activities.

### PREREQUISITES

Familiarity with the MD sector

### ACCESS

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

### COURSE CONTENT

1. Overview of Regulation (EU) 2017/745
2. Obligations of economic operators
3. EUDAMED & UDI
4. Classification of Medical Devices
5. General Safety and Performance Requirements
6. Technical Documentation

### 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

### EVALUATION METHODS

Course evaluation quiz  
Satisfaction survey  
Attendance certificate

This package is assessed based on each individual's acquisition of knowledge via a quiz at the end of each module (*practice quiz*) and one at the end of the 6 modules (*final quiz/success criteria >= 80%*). When trainees pass the final 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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