



Package for QUALITY ASSURANCE

Regulation (EU) 2017/745

REF. E-MDR-F-07 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The QUALITY ASSURANCE package is composed of 7 modules and has been designed specifically to present, in an interactive format, the main obligations of the Quality Assurance Department to ensure compliance with Regulation (EU) 2017/745.

DURATION

175 minutes, including 110 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 Quality Assurance Department

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on the Quality Assurance Department's activities

PREREQUISITES

Familiarity with the MD sector

COURSE CONTENT

1. Overview of Regulation (EU) 2017/745
2. Obligations of economic operators
3. Market authorization
4. Classification of Medical Devices
5. Conformity assessment
6. Post-Market Surveillance & Vigilance
7. Quality Management System

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.

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 7 modules (*final quiz/success criteria* $\geq 80\%$). 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!

Email: formation@ceiso.fr

Tel.: +33 6 42 58 94 52