CEISO
TRAINING CENTER

NEW

Package for MANUFACTURERS

Regulation (EU) 2017/745

REF. E-MDR-F-01 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The MANUFACTURERS' package is composed of 11 modules and has been designed specifically to present, in an interactive format, the main obligations of Medical Device (MD) manufacturers to ensure compliance with Regulation (EU) 2017/745.

DURATION

310 minutes, including 200 minutes of lessons and 110 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 MD manufacturers

EDUCATIONAL GOALS

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

PREREQUISITES

Familiarity with the MD sector

COURSE CONTENT

1. Overview of Regulation (EU) 2017/745
2. Obligations of economic operators
3. EUDAMED & UDI
4. Market authorization
5. Classification of Medical Devices
6. Conformity assessment
7. General Safety and Performance Requirements
8. Technical Documentation
9. Clinical Evaluation
10. Post-Market Surveillance & Vigilance
11. Quality Management System

ACCESS

The CEISO ACADEMY platform can be accessed for a period of six 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 11 modules *(final quiz/success criteria >= 80%)*. If 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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