

REF. E-MDR-MOD-09 - E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Clinical Evaluation module presents the clinical evaluation methodology and the data to be used for this evaluation.

DURATION

37 minutes, including a 25-minute lesson and 12 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 (N.B. covered in the Overview module)

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

- Learn the methodology for a clinical evaluation
- Know which data to use and how to obtain it
- Know how to analyze and organize clinical data to comply with regulatory requirements

Clinical Evaluation

Regulation (EU) 2017/745

COURSE CONTENT

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

- 1. Clinical evaluation objectives and methodology
- 2. Nature, source and equivalence of the data
- 3. Clinical evaluation report

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 >= 80%). If trainees pass the quiz, they receive their training certificate, as well as the corrected quiz, by email.



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