CEISO
TRAINING CENTER

REF. ST02 - INTRA/INTER

PROCESSES

Medical Devices: Ethylene Oxide Sterilization - Application of EN ISO 11135

COURSE DESCRIPTION

International regulations that govern market authorizations for Medical Devices require process control, including notably for sterilization processes.

By applying EN ISO 11135, control of the ethylene oxide sterilization process for medical devices is ensured.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Understand the principles for validation and control of the ethylene oxide sterilization process.
- Be able to release sterile batches
- Be able to draw up specifications with the providers involved
- Control the impact of changes on the products

TARGET TRAINEES

Medical Device manufacturers/ subcontractors, and more particularly:

- R&D
- Methods
- Production
- Quality Control - Release

PREREQUISITES

- Process qualification concepts
- Some familiarity with microbiology may help better understand the principles relative to the control of sterilization processes

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Normative references
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Sterilization processes - General aspects, process validation principles
2. A few definitions
3. Ethylene oxide sterilization
   a. Description of the equipment
   b. Process steps
   c. Control parameters
   d. Validation methodology
   e. Process maintenance - revalidation
   f. Change control
   g. Subcontracting - Specifications
4. Summary/Q&A
5. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program *(success criteria >= 75%).*

Do you have a question? Contact us!
Email: formation@ceiso.fr
Tel.: +33 6 42 58 94 52

CEISO
TRAINING CENTER

REF. ST03 - INTRA/INTER

PROCESSES

Medical Devices: Ionizing Radiation Sterilization - Application of EN ISO 11137

COURSE DESCRIPTION

International regulations that govern market authorization for Medical Devices require process control, including notably for sterilization processes.

By applying EN ISO 11137, control of the ionizing radiation sterilization process for medical devices is ensured.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Understand the principles for validation and control of the ionizing radiation sterilization process
- Be able to release sterile batches
- Be able to draw up specifications with the providers involved
- Control the impact of changes on the products

TARGET TRAINEES

Medical Device manufacturers/ subcontractors, and more particularly:

- R&D
- Methods
- Production
- Quality Control - Release

PREREQUISITES

- Process qualification concepts
- Some familiarity with microbiology may help better understand the principles relative to the control of sterilization processes

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Normative references
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Sterilization processes - General aspects, process validation principles
2. A few definitions
3. Sterilization by ionizing radiation
   a. Description of the equipment
   b. Process steps
   c. Control parameters
   d. Validation methodologies
   e. Process maintenance
      i. Dose audit
      ii. Source recharging
   f. Change control
   g. Subcontracting - Specifications
4. Summary/Q&A
5. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program *(success criteria >= 75%).*

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CEISO
TRAINING CENTER

REF. ST04 - INTRA/INTER

PROCESSES

Medical Devices: Moist Heat Sterilization - Application of EN ISO 17665-1

COURSE DESCRIPTION

International regulations that govern market authorization for Medical Devices require process control, including notably for sterilization processes.

By applying EN ISO 17665-1, control of the moist heat sterilization process for medical devices is ensured.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Understand the principles for validation and control of the moist heat sterilization process
- Be able to release sterile batches
- Be able to draw up specifications with the providers involved
- Control the impact of changes on the products

TARGET TRAINEES

Medical Device manufacturers/ subcontractors, and more particularly:

- R&D
- Methods
- Production
- Quality Control - Release

PREREQUISITES

- Process qualification concepts
- Some familiarity with microbiology may help better understand that principles relative to the control of sterilization processes

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Normative references
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Sterilization processes - General aspects, process validation principles
2. A few definitions
3. Moist heat sterilization
   a. Description of the equipment
   b. Process steps
   c. Control parameters
   d. Validation methodology
   e. Process maintenance - revalidation
   f. Change control
   g. Subcontracting - Specifications
4. Summary/Q&A
5. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program *(success criteria >= 75%).*

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CEISO
TRAINING CENTER

REF. ST05 - INTRA/INTER

PROCESSES

Medical Devices: Dry Heat Sterilization - Application of EN ISO 20857

COURSE DESCRIPTION

International regulations that govern market authorization for Medical Devices require process control, including notably for sterilization processes.

By applying EN ISO 20857, control of the dry heat sterilization process for medical devices is ensured.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Understand the principles for validation and control of the dry heat sterilization process.
- Be able to release sterile batches
- Be able to draw up specifications with the providers involved
- Control the impact of changes on the products

TARGET TRAINEES

Medical Device manufacturers/ subcontractors, and more particularly:
- R&D
- Methods
- Production
- Quality Control - Release

PREREQUISITES

- Process qualification concepts
- Some familiarity with microbiology may help better understand that principles relative to the control of sterilization processes

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Normative references
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Sterilization processes - General aspects, process validation principles
2. A few definitions
3. Sterilization by dry heat
   a. Description of the equipment
   b. Process steps
   c. Control parameters
   d. Validation methodology
   e. Process maintenance - revalidation
   f. Change control
   g. Subcontracting - Specifications
4. Summary/Q&A
5. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program *(success criteria >= 75%).*

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CEISO
TRAINING CENTER

NEW

Overview of the European Medical Device Regulation

Regulation (EU) 2017/745

REF. E-MDR-MOD-01 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Overview of the European Medical Device Regulation module presents the vocabulary and general principles of Regulation (EU) 2017/745.

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

No prerequisite

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.

EDUCATIONAL GOALS

- Learn the vocabulary and scope of the Regulation
- Become familiar with the major points of the Regulation
- Become aware of the parties governed by the Regulation

COURSE CONTENT

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

1. Definitions
2. Scope
3. Structure of the regulation
4. Parties involved

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 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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CEISO
TRAINING CENTER

NEW

Obligations of Economic Operators

Regulation (EU) 2017/745

REF. E-MDR-MOD-02 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Obligations of Economic Operators module presents the parties who are governed by Regulation (EU) 2017/745 and the obligations incumbent on economic operators active on the Medical Device (MD) market

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.

EDUCATIONAL GOALS

- Become familiar with the economic operators on the medical device market
- Identify the obligations incumbent on each of these operators

COURSE CONTENT

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

1. Parties involved
2. Manufacturer's obligations
3. Authorized representative's obligations
4. Importer's obligations
5. Distributor's obligations

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 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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CEISO
TRAINING CENTER

NEW

EUDAMED & UDI

Regulation (EU) 2017/745

REF. E-MDR-MOD-03 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The EUDAMED & UDI module presents the EUDAMED database and different types of device identifiers

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

No prerequisite

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.

EDUCATIONAL GOALS

- Understand EUDAMED and the main principles for entry into this database
- Become familiar with the different types of UDIs and their requirements

COURSE CONTENT

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

1. EUDAMED
2. UDI

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 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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CEISO
TRAINING CENTER

NEW

Market Authorization

Regulation (EU) 2017/745

REF. E-MDR-MOD-04 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Market Authorization module presents the principles and steps to take to place Medical Devices (MD) on the market

DURATION

16 minutes, including a 10-minute lesson and 6 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.

EDUCATIONAL GOALS

- Learn the principles that govern market authorizations for Medical Devices
- Become familiar with the market authorization conditions and steps for a Medical Device

COURSE CONTENT

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

1. Regulatory requirements
2. Market authorization steps
3. Parties involved

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 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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CEISO
TRAINING CENTER

NEW

Classification of Medical Devices

Regulation (EU) 2017/745

REF. E-MDR-MOD-05 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Classification of Medical Devices (MD) module presents the different MD classes and the classification rules.

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 regarding market authorization (N.B. covered in the Overview and Market Authorization 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

- Understand what the different classes of medical devices refer to
- Know how to assign the right class to the different types of devices
- Become familiar with the principal special rules

COURSE CONTENT

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

1. Medical Device classes
2. Non-invasive devices
3. Invasive devices
4. Active devices
5. Special rules

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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CEISO
TRAINING CENTER

NEW

Conformity Assessment

Regulation (EU) 2017/745

REF. E-MDR-MOD-06 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Conformity Assessment module presents the procedures to assess conformity and the Technical Documentation's sampling principles in the framework of this assessment.

DURATION

16 minutes, including a 10-minute lesson and 6 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 regarding market authorization, as well as classification and UDI rules (N.B. covered in the Overview, EUDAMED and UDI, Market Authorization and MD Classification 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.

EDUCATIONAL GOALS

- Understand the conformity assessment procedures for medical devices according to Regulation (EU) 2017/745
- Understand the Technical Documentation's sampling principles in the framework of Medical Device conformity assessments

COURSE CONTENT

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

1. Preamble
2. Conformity assessment procedures
3. Technical Documentation assessment via sampling
4. Quality Management System evaluation

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 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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CEISO
TRAINING CENTER

NEW

General Safety and Performance Requirements

Regulation (EU) 2017/745

REF. E-MDR-MOD-07 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The General Safety and Performance Requirements (GSPR) module presents the safety and performance, design and manufacturing requirements and the information that must be provided with a Medical Device (MD).

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

- Become familiar with the safety and performance requirements set out in Annex I of the Regulation
- Differentiate the general requirements from those regarding performance, design and manufacturing
- Be aware of the information to be provided with an MD

COURSE CONTENT

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

1. General requirements
2. Performance, design and manufacturing requirements
3. Requirements relative to information provided with the device

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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CEISO
TRAINING CENTER

NEW

Technical Documentation

Regulation (EU) 2017/745

REF. E-MDR-MOD-08 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Technical Documentation module presents the content of the Technical Documentation and the information in the documentation regarding post-market surveillance.

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, and more particularly the General Safety and Performance Requirements (N.B. covered in the Overview and GSPR 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.

EDUCATIONAL GOALS

- Familiarity with the Regulation's Annexes that set out the content of the Technical Documentation (TD)
- Familiarity with the requirements in terms of the TD content for the EU conformity declaration
- Familiarity with the documentation's elements on post-market surveillance

COURSE CONTENT

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

1. Prerequisites for the conformity declaration (Annex II)
2. Post-market surveillance (Appendix III)

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 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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CEISO
TRAINING CENTER

NEW

Clinical Evaluation

Regulation (EU) 2017/745

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.

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

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

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 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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CEISO
TRAINING CENTER

NEW

Post-Market Surveillance & Vigilance

Regulation (EU) 2017/745

REF. E-MDR-MOD-10 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Post-Market Surveillance & Vigilance module describes the purpose of post-market surveillance and the procedures to implement based on the type of data collected.

DURATION

30 minutes, including a 20-minute lesson and 10 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, more particularly those regarding product classification and the principles to demonstrate and monitor clinical benefits (N.B. covered in the Overview, MD Classification and Clinical Evaluation 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

- Understand the need for post-market surveillance
- Become familiar with the procedures to apply based on the type of data collected

COURSE CONTENT

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

1. Post-market surveillance (PMS)
2. Claim processing
3. Vigilance
4. Processing other relevant information
5. Post-market clinical follow-up (PMCF)

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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CEISO
TRAINING CENTER

NEW

Quality Management System

Regulation (EU) 2017/745

REF. E-MDR-MOD-10 – 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 >= 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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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.

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NEW

Package for DISTRIBUTORS

Regulation (EU) 2017/745

REF. E-MDR-F-02 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The DISTRIBUTORS' package is composed of 7 modules and has been designed specifically to present, in an interactive format, the main obligations of Medical Device distributors to ensure compliance with Regulation (EU) 2017/745.

DURATION

195 minutes, including 125 minutes of lessons and 70 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 distributors

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on distribution 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. 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 >= 80%)*. If trainees pass the final quiz, they receive their training certificate, as well as the corrected quiz, by email.

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NEW

Package for IMPORTERS

Regulation (EU) 2017/745

REF. E-MDR-F-03 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The IMPORTERS' package is composed of 7 modules and has been designed specifically to present, in an interactive format, the main obligations of Medical Device importers to ensure compliance with Regulation (EU) 2017/745.

DURATION

195 minutes, including 125 minutes of lessons and 70 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 importers

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on importing 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. Post-Market Surveillance & Vigilance
7. Quality Management System

ACCESS

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

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NEW

Package for AUTHORIZED REPRESENTATIVES

Regulation (EU) 2017/745

REF. E-MDR-F-04 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The AUTHORIZED REPRESENTATIVES' package is composed of 9 modules and has been designed specifically to present, in an interactive format, the main obligations of authorized representatives of Medical Devices to ensure compliance with Regulation (EU) 2017/745.

DURATION

235 minutes, including 150 minutes of lessons and 85 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 authorized representatives of MD

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on authorized representatives' 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. Technical Documentation
8. Post-Market Surveillance & Vigilance
9. 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 9 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.

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NEW

Package for REGULATORY AFFAIRS

Regulation (EU) 2017/745

REF. E-MDR-F-05 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The REGULATORY AFFAIRS package is composed of 11 modules and has been designed specifically to present, in an interactive format, the main Regulatory Affairs obligations 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 Regulatory Affairs Departments

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on the Regulatory Affairs Department

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.

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CEISO
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NEW

Package for RESEARCH & DEVELOPMENT

Regulation (EU) 2017/745

REF. E-MDR-F-06 – E-LEARNING

EUROPEAN REGULATIONS

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

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

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 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.

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CEISO
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NEW

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

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CEISO
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NEW

Package for CLINICAL DEPARTMENTS

Regulation (EU) 2017/745

REF. E-MDR-F-08 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The CLINICAL DEPARTMENTS' package is composed of 5 modules and has been designed specifically to present, in an interactive format, the main obligations of the Clinical Department to ensure compliance with Regulation (EU) 2017/745.

DURATION

155 minutes, including 100 minutes of lessons and 55 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 Clinical Department

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on the Clinical Department's 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. Classification of Medical Devices
3. General Safety and Performance Requirements
4. Clinical Evaluation
5. Post-Market Surveillance & Vigilance

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 5 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.

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CEISO
TRAINING CENTER

REF. E-MDR-F-09 – E-LEARNING

EUROPEAN REGULATIONS

NEW

Package for PRODUCTION/PURCHASING

Regulation (EU) 2017/745

COURSE DESCRIPTION

The Production/Purchasing package is composed of 5 modules and has been designed specifically to present, in an interactive format, the main obligations of the Production and Purchasing Departments to ensure compliance with Regulation (EU) 2017/745.

DURATION

150 minutes, including 95 minutes of lessons and 55 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 Production/Purchasing Departments

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on the Production/Purchasing Departments' 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. EUDAMED & UDI
3. General Safety and Performance Requirements
4. Technical Documentation
5. Quality Management System

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 5 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.

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CEISO
TRAINING CENTER

NEW

Package for SALES DEPARTMENTS

Regulation (EU) 2017/745

REF. E-MDR-F-10 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The SALES DEPARTMENTS' package is composed of 6 modules and has been designed specifically to present, in an interactive format, the main obligations of the Sales Department to ensure compliance with Regulation (EU) 2017/745.

DURATION

170 minutes, including 110 minutes of lessons and 60 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 Sales Department

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on the Sales Department's 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. Market authorization
5. Post-market surveillance & vigilance
6. Quality Management System

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.

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