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%).*

Do you have a question? Contact us!
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