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%).*

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