Master the sterilization of medical devices
Validation of sterilization by ethylene oxide

GOAL

- Learn the methodological bases and the necessary technical tools and documentation for implementing the validation, control and audit of ethylene oxide sterilization processes

AUDIENCE

- Medical device manufacturers
- Sterilization responsible staff and managers
- Quality managers
- Technical managers
- Engineers
- Production staff wishing to deepen their theoretical and practical knowledge

PREREQUISITES

- Theoretical knowledge of standards ISO 11137-1 and / or a first experience in sterilization

MATERIALS AND TEACHING RESOURCES

- Presentation Slides
- Case studies
- Full binder with presentation slides
- Session survey
- Breaks and lunches with all participants to share experiences and learnings

EVALUATION PROCEDURES

- This training does not lead to a formal assessment
- A customer satisfaction questionnaire is given at the end of the training

CONTENT

DAY 1 /// 9 : 30 AM - 05 : 30 PM

- Welcome and Opening
- Control and management of the process
  - Definitions, reference documents
  - Packaging process
  - Water quality, quality of solvents and reagents, residue control
  - Environmental controlled area
  - Assembly and packaging, packaging compatibility
- Microbiological testing contributing to the sterilization validation
  - Definitions, reference documents
  - Validation of the microorganisms’ recovery technique
  - Estimation of the microorganisms’ population
  - Determination beyond initial contamination
- Sterilization by ethylene oxide
  - Principle, reference documents
  - Cycle phases
- Operational Qualification - Physical
- Operational Qualification – Microbiological
- Metrology physical quantities
- Establishment of the validation report
- Product release
- Traditional release
- Parametric release
- Control ETO residual EC

DAY 2 /// 9 : 00 AM - 5 : 00 PM

- Radiation sterilization (continued)
- Safety control
  - Pyrogericity tests
  - Biological tests
- Discussion, conclusion, assessment of training
- Hourly distribution between two days for guidance

ADVANTAGES

- Trainer experience
- Focus on the important points of the standard

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Keynote speakers
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