Master the sterilization of medical devices
Validation of sterilization by irradiation

GOAL
- Learn the methodological bases and the necessary technical tools and documentation for implementing the validation, control and audit of radiation 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 ISO 11137-2 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 microbiorganisms’ recovery technique
  - Estimation of the microbiorganisms’ population
  - Determination of the initial contamination
  - Sterilization by irradiation
  - Principle, reference documents

DAY 2 /// 9 : 00 AM - 5 : 00 PM
- Types of radiation
- Installation - Qualification
- Choice of the sterilization dose: specific sterilization dose to a product
- Applying a minimal dose of 25 kGy
- Metrology, traceability to national standards, qualification of irradiation installation
- Dosimetry systems
- Validation

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

Course director
Charles-Alban GRANDIERE
Implantable medical devices department manager
G-MED certification division
Certification and Standards Department - LNE

Keynote speakers
Abdess NAJI
Consultant, auditor, expert

Reference
SA 27 A

2 DAYS /// 14 HOURS

CONTACT US

2017