ISO 11137 – Radiation Sterilization Practitioner Training

Course Description

The ISO 11137 – Radiation Sterilization Practitioner Training is a 5-day intensive technical program designed for medical device professionals, quality managers, validation engineers, and regulatory specialists responsible for sterilization processes.

This course provides in-depth coverage of ISO 11137 Parts 1, 2, and 3, focusing on gamma radiation sterilization, dose establishment methodologies, validation lifecycle (IQ/OQ/PQ), microbiological considerations, routine control, dose audits, and regulatory expectations.

Blending theoretical knowledge with structured simulation workshops and real-world case studies, participants will gain practical competence in designing, validating, monitoring, and auditing radiation sterilization processes.

The program prepares professionals to confidently manage sterilization validation projects, ensure regulatory compliance, and maintain sterility assurance levels in medical device manufacturing environments.

Course Audience

• Quality Assurance (QA) Managers
• Regulatory Affairs (RA) Professionals
• Validation Engineers
• Sterilization Process Owners
• Medical Device Manufacturers
• ISO 13485 Professionals

• Auditors and Compliance Specialists
• Contract Sterilization Service Providers

Course Objectives

1. Understand the structure and scope of ISO 11137 Parts 1, 2, and 3.
2. Learn the fundamentals of radiation sterilization (gamma, E-beam, X-ray).
3. Understand Sterility Assurance Level (SAL) concepts and risk-based thinking.
4. Explore sterilization dose establishment methodologies (VDmax, Method 1, etc.).
5. Gain knowledge of bioburden testing and microbiological considerations.
6. Learn validation lifecycle stages: IQ, OQ, PQ.
7. Understand dose mapping and dosimetry principles.
8. Explore routine monitoring and dose audit programs.
9. Manage outsourced sterilization services effectively.
10. Interpret regulatory expectations under MDR and FDA.
11. Develop sterilization validation documentation.
12. Conduct risk assessments for radiation sterilization processes.
13. Identify non-conformities and corrective actions.
14. Prepare for audits and regulatory inspections.
15. Design sterilization control strategies aligned with ISO 13485.

16. Understand change control in sterilization processes.
17. Analyze failure scenarios and investigation techniques.
18. Apply statistical concepts relevant to dose establishment.
19. Build a compliant sterilization validation master plan.
20. Strengthen practical competence through simulation exercises.

Course Prerequisites

1. Basic knowledge of medical device manufacturing.
2. Familiarity with ISO 13485 quality management systems.
3. Understanding of validation concepts.
4. Awareness of regulatory frameworks (FDA/MDR preferred).
5. Basic understanding of microbiology (advantageous but not mandatory).
6. Experience in QA/RA/Production roles.
7. Knowledge of risk management principles (ISO 14971 familiarity beneficial).
8. Ability to interpret technical documentation.
9. Interest in sterilization process control.
10. Willingness to participate in workshops and case studies.

Learning Outcomes

1. Design and validate gamma radiation sterilization processes.
2. Apply dose establishment methodologies effectively.
3. Develop complete sterilization validation documentation.

4. Implement robust routine monitoring and dose audit programs.
5. Interpret microbiological data for sterility assurance.
6. Manage outsourced sterilization providers confidently.
7. Prepare organizations for regulatory inspections.
8. Identify gaps in sterilization compliance frameworks.
9. Integrate sterilization controls into ISO 13485 systems.
10. Develop practical solutions to real-world sterilization challenges.
11. Improve product safety and regulatory readiness.
12. Strengthen organizational resilience through validated sterilization controls.

Detailed TOC

Day 1: Fundamentals of Radiation Sterilization

1. Introduction to Sterilization of Medical Devices

1.1 Importance of Sterilization in Healthcare Products
1.2 Overview of Sterilization Methods
1.3 Comparison: Gamma vs E-Beam vs X-ray
1.4 Regulatory Expectations (FDA, EU MDR)
1.5 Relationship with ISO 13485
1.6 Introduction to ISO 11137 Structure
1.7 Case Study: Sterilization Failure Impact

2. Fundamentals of Radiation Science

2.1 Basics of Ionizing Radiation
2.2 Cobalt-60 and Gamma Radiation

2.3 Radiation Interaction with Microorganisms
2.4 Understanding Sterility Assurance Level (SAL)
2.5 D10 Value and Microbial Reduction
2.6 Risk-Based Approach to Sterilization

Day 2: ISO 11137 – Part 1 Requirements

3. Development and Validation Requirements

3.1 Scope and Application
3.2 Product Families and Grouping
3.3 Process Definition
3.4 Risk Assessment in Sterilization
3.5 Responsibilities and Documentation

4. Validation Lifecycle

4.1 Installation Qualification (IQ)
4.2 Operational Qualification (OQ)
4.3 Performance Qualification (PQ)
4.4 Validation Report Requirements
4.5 Workshop: Drafting a Validation Plan

Day 3: Dose Establishment & Microbiology

5. ISO 11137 Part 2 – Establishing the Sterilization Dose

5.1 Overview of Dose Establishment Methods
5.2 VDmax Method
5.3 Method 1
5.4 Sample Size and Statistical Considerations
5.5 Verification Dose Experiments
5.6 Workshop: Dose Calculation Simulation

6. Microbiological Considerations

6.1 Bioburden Determination
6.2 Microbial Identification
6.3 Sterility Testing Principles
6.4 Environmental Monitoring
6.5 Managing Microbial Variability
6.6 Case Study: Bioburden Excursion Investigation

Day 4: Routine Control and Audit Readiness

7. ISO 11137 Part 3 – Dosimetry and Dose Mapping

7.1 Dosimeter Types
7.2 Dose Mapping Techniques
7.3 Uniformity Ratio
7.4 Worst-Case Configuration
7.5 Workshop: Dose Mapping Exercise

8. Routine Monitoring and Dose Audits

8.1 Routine Process Control
8.2 Periodic Dose Audits
8.3 Requalification Requirements
8.4 Handling Non-Conformities
8.5 Change Control in Sterilization
8.6 Case Study: Dose Audit Failure

Day 5: Strategic Integration and Practical Application

9. Managing Outsourced Sterilization

9.1 Supplier Qualification
9.2 Technical Agreements
9.3 Audit Checklist for Sterilization Providers
9.4 Risk-Based Supplier Monitoring

10. Regulatory Inspections and Compliance

10.1 What Auditors Look For
10.2 Common Observations and Findings
10.3 Documentation Review Techniques
10.4 CAPA Management in Sterilization

11. Simulation Exercises and Capstone Project

11.1 Exercise 1: Build a Sterilization Validation Master Plan
11.2 Exercise 2: Design a Dose Audit Program
11.3 Exercise 3: Risk Assessment for Sterilization Failure
11.4 Exercise 4: Mock Regulatory Inspection Simulation
11.5 Final Assessment & Knowledge Review