Advanced Sterilization and Depyrogenation Methods Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

This advanced course is a critical and comprehensive deep-dive into the science and regulatory compliance of achieving Sterility Assurance Level (SAL) and Endotoxin Reduction within the pharmaceutical and medical device industries. With global regulatory bodies, including the FDA, EMA, and WHO, continually raising the bar for aseptic processing and contamination control, professionals must master the latest validation protocols and cutting-edge methods beyond standard steam sterilization.

Advanced Sterilization and Depyrogenation Methods Training Course directly addresses the need for Subject Matter Experts (SMEs) capable of designing, validating, troubleshooting, and auditing the complex systems like dry heat tunnels, isolators, and VHP chambers that ensure patient safety and prevent catastrophic product recalls. It is the essential next step for individuals looking to elevate their expertise in quality assurance and manufacturing operations.

Programme Curriculum

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Course Objectives

Upon completion, participants will be able to:

1. Master the calculation and application of F0, Fh, and D/Z-values for advanced thermal processing.
2. Design and validate Dry Heat Depyrogenation cycles to achieve a ?ëÑ3-log Endotoxin Reduction.
3. Evaluate and implement Vaporized Hydrogen Peroxide (VHP) and Ethylene Oxide (EtO) sterilization for complex load configurations and sensitive materials.
4. Navigate the current EU GMP Annex 1 and FDA Guidance on aseptic manufacturing and terminal sterilization.
5. Perform Root Cause Analysis (RCA) for common sterilization and depyrogenation deviations
6. Develop and execute Installation (IQ), Operational (OQ), and Performance Qualification (PQ) protocols for critical equipment.
7. Select appropriate Biological and Chemical Indicators and Endotoxin Challenge Vials (ECVs) based on a risk-based approach.
8. Understand the kinetics and mechanism of endotoxin destruction vs. removal
9. Implement parametric release strategies, moving away from reliance on end-product sterility testing.
10. Apply Quality by Design (QbD) principles to sterilization process development and control.
11. Lead and defend sterilization/depyrogenation sections during regulatory audits and inspections.
12. Design effective sterilizing filtration and subsequent filter integrity testing
13. Establish and monitor effective environmental monitoring and contamination control programs to support sterility.

Target Audience

1. Validation Engineers
2. Quality Assurance (QA) & Quality Control (QC) Specialists
3. Aseptic Processing Supervisors & Managers
4. Manufacturing & Operations Personnel in sterile product areas
5. Regulatory Affairs Professionals
6. Microbiologists responsible for Bacterial Endotoxin Testing and Bioburden monitoring
7. Equipment Calibration and Maintenance Technicians
8. Internal GxP Auditors and Consultants

Course Modules

Module 1: Foundational Principles of Sterility and Pyrogenicity

- Sterilization, Disinfection and Depyrogenation.
- Microbial Inactivation Kinetics
- Pyrogens and Endotoxins

- Case Study: Analyzing a product failure where a low Bioburden product failed sterility testing, pointing to potential Aseptic Processing issues.
- Regulatory Framework

Module 2: Advanced Moist Heat Sterilization

- Temperature, pressure, time, and steam quality
- Load Configuration and Thermal Mapping
- F0 Value calculation and the concept of Overkill vs. Bioburden/Half-Cycle Method.
- Causes and remediation for wet loads and BI failures.
- Case Study: Recalculating F0 values after an unexpected drop in chamber temperature during a cycle, and determining batch disposition.

Module 3: Dry Heat Depyrogenation and Tunnel Qualification

- Mechanism of Endotoxin Destruction.
- Depyrogenation Tunnel design, HEPA filtration, and air flow mapping.
- Endotoxin Challenge Study protocol
- Air Velocity and Temperature Uniformity/Penetration mapping.
- Case Study: Reviewing the DQ/IQ/OQ/PQ of a new dry heat tunnel and the impact of tunnel speed on D-value reduction.

Module 4: Ethylene Oxide (EtO) Sterilization

- EtO Gas chemistry, critical cycle parameters
- Material compatibility and residual limit testing
- Full-cycle and Half-cycle approach and resistance variability.
- Importance and validation of the degasification process.
- Case Study: Investigating a process deviation where product load density was increased, resulting in higher-than-acceptable EtO residuals.

Module 5: Vaporized Hydrogen Peroxide (VHP) Sterilization

- Vapor Phase and Plasma sterilization.
- Use in Isolators, Restricted Access Barrier Systems, and Cleanroom Decontamination.
- Gassing concentration, residence time, and moisture control.
- VHP Biological Indicators and the challenges of Material Compatibility.
- Case Study: Developing a new VHP cycle for a sensitive pre-filled syringe component inside an isolator system.

Module 6: Sterilizing Filtration for Liquids

- Sieving and Adsorption and the 0.22??m rating standard.
- Materials, pore size, and compatibility with the drug product.
- Filter Integrity Testing
- Brevundimonas diminuta challenge testing.
- Case Study: A filter fails the post-use integrity test; performing an RCA to determine if the batch should be rejected or released.

Module 7: Aseptic Processing and Environmental Control

- Components preparation and final filling processes.

- Cleanroom Classification and Gowning Procedures.
- Environmental Monitoring Program.
- Contamination Control Strategy as per EU GMP Annex 1.
- Case Study: Analyzing EM trend data showing an excursion in a Grade B area and designing the resulting CAPA.

Module 8: Qualification Documentation (IQ, OQ, PQ)

- Defining the scope and acceptance criteria for all qualification phases.
- Developing detailed SOPs and Preventive Maintenance schedules post-OQ.
- Execution of Performance Qualification and establishing routine monitoring.
- Validation Master Plan structure and content for sterility processes.
- Case Study: Writing the final Validation Report for a new autoclave installation, compiling all IQ/OQ/PQ data.

Module 9: Endotoxin Reduction Beyond Dry Heat

- Methods of Endotoxin Removal.
- Alkaline/Acid Hydrolysis and Oxidation for depyrogenation of non-glassware materials.
- Validation of Water for Injection system depyrogenation controls.
- Limulus Amebocyte Lysate Testing methods.
- Case Study: Selecting the optimal depyrogenation method for new elastomeric closures

Module 10: Regulatory and GxP Compliance

- Interpreting FDA 21 CFR Part 211 and EU GMP Annex 1 requirements.
- Defending SAL claims and validation data during regulatory inspections.
- Handling and responding to 483s and Warning Letters related to sterility failures.
- International standards
- Case Study: Role-playing a regulatory inspection where the lead auditor challenges the facility's VHP cycle re-qualification frequency.

Module 11: Statistical Methods and Parametric Release

- Use of Statistical Process Control in sterilization monitoring.
- The concept and requirements for Parametric Release.
- Statistical justification for sample sizes in validation and routine testing.
- Applying tolerance limits and control charts to critical process parameters (CPPs).
- Case Study: Transitioning a product from traditional End-Product Sterility Testing to a fully validated Parametric Release program.

Module 12: Root Cause Analysis (RCA) and CAPA

- Structured RCA methodologies.
- Investigating Sterility Test Failures and Endotoxin Excursions.
- Developing effective and measurable Corrective and Preventive Actions.
- The role of Quality Risk Management in deviation handling.
- Case Study: Leading an RCA investigation following a positive Biological Indicator result in a routine autoclave load.

Module 13: Single-Use Systems (SUS) Sterilization

- Sterilization and depyrogenation of single-use components and assemblies.
- Compatibility challenges with common sterilization methods.
- Extractables and leachables considerations for SUS.
- Supplier qualification and audit for Pre-Sterilized components.
- Case Study: Assessing the E&L risk when switching from stainless steel to a complex single-use bioreactor bag assembly.

Module 14: Sterilization of Medical Devices

- Distinctions between pharmaceutical and Medical Device Sterilization requirements.
- ISO 13485 and specific standards
- Selection of the appropriate method based on material and design complexity.
- Bioburden-based and Overkill dose setting for radiation sterilization.
- Case Study: Designing a sterilization validation protocol for a new Class III implantable device.

Module 15: Quality by Design (QbD) in Sterility Assurance

- Defining the Target Product Profile and Critical Quality Attributes related to sterility.
- Identifying Critical Process Parameters and Critical Material Attributes
- Developing a Design Space for sterilization and depyrogenation cycles.
- Implementing Process Analytical Technology for real-time monitoring.
- Case Study: Applying QbD principles to optimize a freeze-drying cycle where primary packaging integrity is a CQA.

Training Methodology

The course employs an intensive, hands-on, blended learning approach, utilizing:

- Interactive Lectures.
- Case Studies & Workshops.
- Group Exercises.
- Regulatory Scenarios

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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