Advanced Cleaning Validation for Multi-Product Facilities 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

Advanced Cleaning Validation for Multi-Product Facilities Training Course is specifically designed to address the complex challenges of cleaning validation in modern multi-product pharmaceutical and biotechnology facilities. Regulatory scrutiny is intensifying, demanding a science- and risk-based approach to prevent cross-contamination and ensure patient safety. The course moves beyond basic principles, diving deep into the lifecycle approach to validation as mandated by current FDA and EMA guidelines, including the critical aspects of Health-Based Exposure Limits (HBELs) and Permitted Daily Exposure (PDE). Participants will master the methodologies for managing shared equipment, developing worst-case protocols, and integrating data integrity into their validation programs.

The pharmaceutical manufacturing landscape is characterized by high-volume, flexible production that frequently involves multiple active ingredients processed on the same equipment. This necessitates a robust and defensible cleaning validation strategy. Failure to validate cleaning processes correctly is a leading cause of GMP deviations, regulatory citations, and costly product recalls. This program is essential for professionals seeking to implement current best practices in risk-based cleaning validation, optimize their Clean-In-Place (CIP)/manual procedures, ensure audit-readiness, and apply advanced analytical techniques like Total Organic Carbon (TOC) for effective residue detection and monitoring

Programme Curriculum

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Course Objectives

1. Master the latest regulatory expectations for cleaning validation
2. Develop and justify Health-Based Exposure Limits (HBELs), including Acceptable Daily Exposure (ADE) and Permitted Daily Exposure (PDE) calculations.
3. Design and execute worst-case product and worst-case equipment selection using a documented risk-based rationale.
4. Implement the cleaning validation lifecycle approach from initial design through to Continued Process Verification (CPV).
5. Establish scientifically sound Maximum Allowable Carryover (MACO) and residue acceptance criteria.
6. Formulate and document comprehensive, audit-ready cleaning validation protocols and final reports.
7. Select and validate appropriate sampling methods and analytical techniques
8. Conduct and interpret cleaning recovery studies to ensure sampling and analytical methods are effective and robust.
9. Define, justify, and manage dirty hold time (DHT) and clean hold time (CHT) limits.
10. Strategize and validate both automated (CIP) and manual cleaning procedures for multi-product equipment trains.
11. Integrate principles of data integrity into all cleaning validation documentation and testing.
12. Effectively troubleshoot and investigate cleaning failures, deviations, and implement effective CAPAs.
13. Prepare the organization for successful regulatory inspections and audits focused on cross-contamination control.

Target Audience

1. Validation Engineers/Specialists.
2. Quality Assurance (QA) Managers/Supervisors.
3. Manufacturing/Production Managers.
4. Quality Control (QC) Laboratory Staff
5. Regulatory Affairs Professionals.

6. Process Development Scientists.
7. Engineers/Technical Services.
8. Internal Auditors/Compliance Specialists.

Course Modules

Module 1: Regulatory and Foundational Requirements

- Review of current global GMP regulations
- Defining the Cleaning Validation Lifecycle.
- Integration with the overall Contamination Control Strategy (CCS).
- Understanding the transition from a traditional to a risk-based approach.
- Case Study: Analyzing recent FDA Warning Letters citing inadequate cleaning validation in multi-product facilities.

Module 2: Health-Based Exposure Limits (HBELs)

- Principles and application of toxicology for cleaning limits.
- Detailed methodology for calculating Acceptable Daily Exposure (ADE).
- Translating ADE into Permitted Daily Exposure (PDE) for different routes of administration.
- Addressing residues of highly potent compounds and new active ingredients.
- Case Study: Calculating the PDE for a new oncological drug in a multi-product facility.

Module 3: Maximum Allowable Carryover (MACO) and Limits

- Derivation of the MACO value using PDE, 1/1000 dose, and 10 ppm criteria.
- Establishing scientifically justified residue acceptance criteria.
- Calculations for different dosage forms and equipment types.
- Dealing with non-uniform residue distribution and carryover in complex systems.
- Case Study: Comparing and justifying cleaning limits for an oral solid dosage (OSD) product and a topical cream processed on the same reactor.

Module 4: Quality Risk Management (QRM) in Cleaning

- Application of ICH Q9 principles to cleaning validation.
- Tools for risk assessment for cleaning processes.
- Identifying and prioritizing worst-case products and worst-case equipment.
- Managing risks associated with bioburden and cleaning agent residues.
- Case Study: Conducting an FMEA on a shared bulk intermediate product transfer line to prioritize cleaning risks.

Module 5: Designing the Cleaning Process

- Principles of detergent and solvent selection for multi-product residues.
- Validation of Clean-In-Place (CIP) systems and parameters
- Developing and standardizing manual cleaning procedures for complex parts.
- Equipment design features that aid or impede effective cleaning.
- Case Study: Optimizing a CIP cycle for a large stainless-steel bioreactor that processes different fermentation products.

Module 6: Cleaning Validation Protocol Development

- Key sections and content requirements for a robust validation protocol.
- Defining the validation strategy and number of successful runs required.
- Establishing revalidation triggers and change control procedures.
- Defining roles, responsibilities, and acceptance criteria in the protocol.
- Case Study: Drafting a protocol for the validation of a shared fluid bed dryer used for three different granules.

Module 7: Sampling Methodology and Validation

- Detailed procedures for swab sampling
- Detailed procedures for rinse sampling
- Selecting representative and difficult-to-clean sampling locations.
- Validation of the sampling recovery method
- Case Study: Designing a scientifically justified sampling plan for a complex homogenizer with hard-to-reach seals and baffles.

Module 8: Analytical Method Validation

- Validation requirements for specific methods
- Validation requirements for non-specific methods
- Determining the Limit of Detection (LOD) and Limit of Quantitation (LOQ).
- Analytical method specificity, linearity, accuracy, and precision.
- Case Study: Comparing the use of TOC versus HPLC for monitoring a highly soluble cleaning agent residue.

Module 9: Dirty and Clean Hold Times

- Scientific rationale for establishing Dirty Hold Time (DHT) limits.
- Scientific rationale for establishing Clean Hold Time (CHT) limits
- Designing and executing hold time studies
- Documentation and regulatory justification for hold time limits.
- Case Study: Justifying a DHT extension for a product susceptible to drying and increased residue adherence.

Module 10: Cleaning Validation Execution and Reporting

- Practical guidance for executing the validation runs and documenting data.
- Handling, investigating, and documenting deviations during validation runs.
- Statistical analysis and interpretation of validation run data.
- Writing the final, legally defensible Cleaning Validation Report.
- Case Study: Analyzing a failed cleaning validation run, identifying the root cause, and documenting the required revalidation.

Module 11: Cleaning Validation Maintenance and CPV

- Implementation of the Continuous Process Verification (CPV) stage for cleaning.
- Developing a risk-based monitoring program for routine cleaning.
- Managing change control and assessing the impact of changes on the validated state.
- Defining the frequency and scope of routine revalidation.
- Case Study: Establishing key performance indicators (KPIs) and alert limits for ongoing cleaning effectiveness monitoring.

Module 12: Data Integrity in Cleaning Validation

- Application of ALCOA+ principles to all cleaning validation records.
- Ensuring data governance for laboratory and manufacturing records.
- Validation of electronic records and audit trails for automated systems
- Best practices for record review, approval, and long-term archiving.
- Case Study: Simulating an audit trail review for a CIP cycle to detect potential data integrity issues.

Module 13: Bioburden and Endotoxin Control

- Establishing scientifically sound microbial acceptance limits for cleaning.
- Validation of sanitization and disinfection procedures.
- Cleaning validation requirements for Aseptic Processing and Annex 1.
- Addressing Endotoxin and Biofilm formation and removal.
- Case Study: Developing a combined cleaning and sanitization protocol for a sterile product API intermediate holding vessel.

Module 14: Special Topics and Advanced Challenges

- Cleaning validation for campaign manufacturing and changeovers.
- Validation of cleaning for non-product contact surfaces where contamination is a risk.
- Strategies for cleaning validation in small-batch and R&D environments.
- The use of Visual Clean as an acceptance criterion and its limitations.
- Case Study: Designing an abbreviated validation program for an R&D suite with frequent, non-commercial product changes.

Module 15: Audit and Inspection Preparedness

- Preparing the Cleaning Validation Master Plan (CVMP) summary document.
- Training staff on how to answer inspector questions related to cleaning.
- Common inspectional pitfalls
- Strategies for defending the risk-based approach to regulatory bodies.
- Case Study: Simulating an FDA PAI (Pre-Approval Inspection) interview scenario on the cleaning validation package.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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