Advanced Viral Inactivation and Removal Studies 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

The biopharmaceutical landscape, particularly in the production of biologics and Advanced Therapy Medicinal Products (ATMPs), is fundamentally dependent on robust viral safety strategies. Contamination with adventitious or endogenous viruses poses an existential risk to product integrity and patient safety. Advanced Viral Inactivation and Removal Studies Training Course is meticulously designed to equip professionals with cutting-edge knowledge and practical skills for designing, executing, and validating viral clearance studies. It moves beyond theoretical foundations to focus on the strategic implementation of orthogonal methods a combination of effective viral inactivation and virus removal steps to achieve the high Log Reduction Values (LRVs) mandated by stringent global regulatory guidelines, including ICH Q5A.

This program provides an in-depth analysis of modern bioprocessing challenges, including the viral safety concerns unique to continuous bioprocessing and gene therapy vectors. Participants will master scale-down model validation, advanced analytical techniques, and risk-based approaches (ICH Q9) to ensure that their manufacturing processes consistently deliver patient-safe therapeutic products. By focusing on process robustness and regulatory compliance, this training is essential for maintaining product quality, accelerating IND/BLA submissions, and safeguarding the reputation of biopharmaceutical organizations in a rapidly evolving, high-stakes industry.

Programme Curriculum

Advanced Viral Inactivation and Removal Studies Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the principles of Orthogonal Viral Clearance strategies for Biologics and ATMPs.
2. Design and Validate Robust Scale-Down Models that accurately predict large-scale manufacturing performance.
3. Implement and Optimize Various Viral Inactivation methods
4. Select and validate high-efficiency Virus Removal techniques, focusing on Nanofiltration and Chromatography.
5. Analyze and Interpret Log Reduction Value (LRV) data to meet specific regulatory acceptance criteria.
6. Apply the requirements of ICH Q5A and current Global Regulatory Frameworks (FDA, EMA) to viral safety programs.
7. Conduct comprehensive Viral Risk Assessments (ICH Q9) for raw materials, cell lines, and process intermediates.
8. Develop an integrated Adventitious Agent and Endogenous Virus control strategy for biomanufacturing.
9. Evaluate the unique Viral Safety Challenges associated with Gene Therapy Vectors and Cell Therapies.
10. Troubleshoot common issues encountered during Viral Spiking Studies and optimize Assay Sensitivity.
11. Prepare high-quality, SEO-Friendly Regulatory Submissions for the viral safety section of drug applications.
12. Integrate Process Analytical Technology (PAT) principles to monitor the Critical Process Parameters (CPPs) of viral clearance steps.
13. Design a compliant and cost-effective Viral Safety Program from Process Development through to Commercial Manufacturing.

Target Audience

1. Process Development Scientists and Engineers.
2. Viral Safety/Virology Specialists and Biotechnologists.
3. Quality Assurance (QA) and Quality Control (QC) personnel in biopharma.
4. Regulatory Affairs Professionals responsible for BLA/IND filings.

5. Downstream Processing (DSP) Managers and Supervisors.
6. Manufacturing Personnel overseeing viral clearance operations.
7. R&D Scientists working on novel biologics and ATMPs.
8. Consultants specializing in Biologics and Biomanufacturing.

Course Modules

Module 1: Foundational Principles of Viral Safety in Bioprocessing

- Overview of regulatory drivers.
- Defining Adventitious and Endogenous viruses
- The concept of Orthogonal Clearance and Process Robustness.
- Introduction to Log Reduction Value calculation and interpretation.
- Risk-based approach to Contamination Control Strategy.
- Case Study: Impact of a Vesivirus contamination event on a commercial-scale facility.

Module 2: Designing and Qualifying Scale-Down Models

- Principles of Hydrodynamic Equivalence and Mass Transfer.
- Critical Process Parameters for scale-down model fidelity.
- Statistical methods for demonstrating scale-down model representativeness.
- Documentation requirements for regulatory submission.
- Hands-on training in scale-down model validation protocols.
- Case Study: Validating a 1/100th scale chromatography model for virus removal.

Module 3: Advanced Low pH Inactivation Kinetics

- Mechanism of Low pH on enveloped virus structure.
- Optimizing pH, Time, and Temperature to maximize LRV.
- Impact of Protein Concentration and Buffer Composition.
- Analysis of inactivation Kinetic Data and Hold Time studies.
- Mitigating protein aggregation and ensuring product stability during low pH treatment.
- Case Study: Optimizing a low pH hold step for a pH-sensitive monoclonal antibody to achieve?ëÑ4 LRV.

Module 4: Solvent/Detergent (S/D) Treatment and Alternatives

- Mechanism of S/D in disrupting lipid-enveloped viruses.
- Selection of appropriate S/D reagents
- Strategies for subsequent S/D Removal from the product stream.
- Non-S/D chemical inactivation methods
- Validation of clearance for Parvoviruses and other non-enveloped species.
- Case Study: Validation of a S/D step in plasma-derived product manufacturing.

Module 5: Nanofiltration Theory and Application

- Principles of Size Exclusion for Virus Removal
- Types of Viral Filters
- Filter Integrity Testing and its limitations.
- Strategies for Pre-Filtration to prevent filter fouling and maximize throughput.
- Validation: Spiking Study design, flow rate, and pressure impact on LRV.
- Case Study: Troubleshooting a low LRV in a nanofiltration step due to pre-filter fouling.

Module 6: Chromatography for Virus Removal

- Multi-Modal and Anion Exchange Chromatography as Viral Reduction steps.
- Mechanisms: Adsorptive Removal
- Optimizing pH and conductivity to enhance virus binding/repulsion.
- Resin and membrane capacity, reuse, and Sanitization Protocols.
- Demonstrating Process Robustness against changes in feed-stream composition.
- Case Study: Using a flow-through AEX step to achieve high LRV against small, non-enveloped viruses.

Module 7: Viral Spiking Studies: Design and Execution

- Selection of Model Viruses based on relevance and process challenge
- Preparation and characterization of High-Titer Virus Stocks.
- Determining Spiking Volume and Infectivity Titer
- Mass balance and accurate sample collection across the unit operation.
- Ensuring the study matrix is representative of the manufacturing intermediate.
- Case Study: Designing a comprehensive spiking study for a multi-step purification process.

Module 8: Viral Assays and Analytical Methods

- Fundamentals of Infectivity Assays
- Molecular methods.
- Addressing Cytotoxicity, Interference, and Limit of Detection.
- Next-Generation Sequencing (NGS) for Adventitious Agent Detection (AAD).
- Validation of analytical assays for sensitivity and accuracy.
- Case Study: Interpreting discrepant results between TCID50?Çï and qPCR for an in-process sample.

Module 9: Regulatory Guidelines and Submission Requirements

- In-depth review of ICH Q5A and its EU/US counterparts.
- Format and content for the viral safety section of IND/BLA/MAA filings.
- Addressing Comparability after process changes or facility transfers.
- Strategy for defining and justifying the Required Overall LRV.
- Preparing for and responding to Regulatory Audit questions on viral safety.
- Case Study: Preparing a response to an FDA query regarding LRV justification for a novel process step.

Module 10: Viral Safety for Advanced Therapies

- Unique viral risks in Cell and Gene Therapy manufacturing.
- Safety considerations for Viral Vectors as products.
- Testing and control of Donor Materials and Cell Banks.
- Mitigation strategies for Replication-Competent Virus
- Specific regulatory expectations for vector-based and Ex Vivo therapies.
- Case Study: Developing a viral safety program for an AAV-based gene therapy product.

Module 11: Risk Management and Adventitious Agent Control

- Conducting a formal Failure Mode and Effects Analysis for viral risks.
- Control strategies for Raw Materials
- Developing a facility-wide Contamination Control Strategy
- Root cause analysis and incident response planning for viral excursion.
- Proactive risk mitigation in Upstream Processing and Downstream Processing

- Case Study: Implementing a viral risk management plan for a facility using High-Risk raw materials.

Module 12: Continuous Bioprocessing and Viral Safety

- Adapting Viral Clearance strategies to Continuous Manufacturing platforms.
- Challenges of integrating viral steps into continuous flow.
- Validation and monitoring of Single-Use systems for viral safety.
- Impact of high throughput and reduced hold times on LRV.
- Real-time and In-Line Monitoring for Process Analytical Technology (PAT).
- Case Study: Redesigning a batch low pH inactivation step for a Continuous Monoclonal Antibody process.

Module 13: Viral Clearance Study Data Analysis and Reporting

- Statistical analysis of LRV data, including uncertainty and confidence intervals.
- Pooling and combining data from multiple experiments and model viruses.
- Writing the final Viral Clearance Study Report for regulatory use.
- Documenting Process Deviations and their impact on LRV.
- Strategies for presenting complex viral safety data to auditors and regulators.
- Case Study: Calculating the overall LRV for a 3-step purification train and justifying the clearance margin.

Module 14: Practical Considerations and Troubleshooting

- Optimizing Viral Filter performance under high protein load.
- Managing Cytotoxicity and Assay Interference in viral assays.
- Best practices for working with High-Containment Viruses.
- GMP considerations for facility design and equipment validation.
- Selecting Surrogate Viruses and justifying their use in validation studies.
- Case Study: Troubleshooting a chromatography step that showed unexpected low LRV in the validation study.

Module 15: Future Trends in Viral Safety

- The role of Artificial Intelligence and Machine Learning in predicting viral clearance.
- Emerging technologies for Viral Inactivation
- Advanced Bioburden and Mycoplasma control in new modalities.
- Platform Approach justification for viral clearance and Process Characterization.
- Harmonization of regulatory expectations for global markets.
- Case Study: Evaluating the implementation of UV-C light inactivation as a novel orthogonal step.

Training Methodology

The training employs a blended, high-engagement approach:

- Interactive Lectures.
- Case Study Analysis.
- Practical Workshops.
- Scenario-Based Simulations.
- Q&A and Expert Panel Discussions.

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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