CONCEPT

Viral Safety and Viral Clearance: Model Viruses, Spiking Studies and LRV Claims

18 – 22 April 2027
Jeddah - Corniche four-star



Viral Safety and Viral Clearance: Model Viruses, Spiking Studies and LRV Claims

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Introduction:

Viral safety and viral clearance failures in biomanufacturing rarely start at the virus filter: they start with an untested raw material, a scale-down column that does not mirror the production step, or a clearance claim that adds log reductions from steps sharing one mechanism. This Core Concept course equips bioprocess, quality, validation and CMC teams to control viral risk across source materials, purification design and product testing, and to defend log reduction values in a filing. Participants produce a Viral Clearance Strategy and Study Plan for a case monoclonal antibody process.

Course Objectives:

- Assess viral contamination risk across cell substrates, raw materials and facility operations using the viral safety triad
- Specify a cell bank, unprocessed bulk and raw material testing programme with suitable adventitious agent methods
- Select relevant and model viruses and match them to the inactivation and removal steps of a purification train
- Qualify scale-down models and design spiking studies that run process steps at worst-case parameter settings
- Calculate log reduction values, cumulative clearance and retrovirus-like particle safety margins and judge which steps can be claimed
- Prepare viral safety documentation for a filing and lead the response when a contamination or clearance failure occurs

Target Audience:

- Downstream process development and MSAT specialists responsible for purification step design and clearance data
- Quality assurance leads responsible for viral risk assessments, deviation decisions and batch disposition
- Quality control and virology testing coordinators responsible for cell bank and bulk harvest test programmes
- Validation specialists responsible for scale-down model qualification and clearance studies run with contract laboratories
- Regulatory CMC specialists responsible for the viral safety sections of product filings

Course Outline:

Day 1: Viral Contamination Risk and the Viral Safety Triad

- Viral Safety Triad: Source Control, Process Clearance Capability and Product Testing
- Endogenous Retrovirus and Adventitious Virus Contamination Routes in Mammalian Cell Culture
- Lessons From Documented Bioreactor Contamination Events With Small Non-Enveloped Viruses
- Animal-Derived Raw Materials, Serum, Trypsin and Media Component Viral Risk Ranking
- Viral Risk Current-State Assessment Checklist for a Biologics Facility

Day 2: Cell Bank Qualification, Raw Material Controls and ICH Q5A Principles

- ICH Q5A Principles: Scope, Cell Substrates of Human or Animal Origin and Case Categories
- Master Cell Bank, Working Cell Bank and End-of-Production Cell Testing Programme
- Adventitious Agent Testing Overview: In Vitro, In Vivo, PCR and Next-Generation Sequencing Methods
- Unprocessed Bulk Harvest Testing and Retrovirus-Like Particle Quantification by Electron Microscopy
- Raw Material Supplier Qualification and Gamma Irradiation or High-Temperature Short-Time Media Treatment

Day 3: Inactivation and Removal Steps and Model Virus Selection

- Relevant, Specific Model and Non-Specific Model Viruses: Selection Matrix by Size, Envelope and Resistance
- Low pH Hold Inactivation: pH, Time, Temperature and Protein Concentration Kinetics
- Solvent/Detergent Inactivation of Enveloped Viruses: Reagent Choice and Mixing Control
- Small-Virus Retentive Filtration: Filter Selection, Flux Decay, Pressure Interruption and Integrity Testing
- Anion Exchange Flow-Through and Protein A Chromatography as Orthogonal Removal Mechanisms

Day 4: Scale-Down Models, Spiking Study Design and Log Reduction Value Calculation

- Scale-Down Model Qualification: Bed Height, Residence Time, Load Ratio and Product Quality Equivalence
- Spiking Study Design: Spike Ratio, Cytotoxicity, Interference Controls and Hold Samples
- Log Reduction Value Calculation From Plaque and TCID50 Titres With Confidence Limits and Large Volume Plating
- Worst-Case Process Parameters: Resin Reuse Cycles, Filter Loading, Conductivity and pH Edges
- Cumulative Clearance Claims, Orthogonality Rules and Retrovirus-Like Particle Safety Margin Calculation

Day 5: Case Study: Viral Clearance Strategy for a Monoclonal Antibody Process

- Case: Monoclonal Antibody Downstream Train Mapping to Viral Clearance Mechanisms
- Case: Failed Virus Filter Integrity Test and Contamination Response Decision Tree
- Filing Documentation: Viral Safety Summary Tables and Clearance Study Reports for the Quality Module
- Viral Clearance Strategy and Study Plan Build for the Case Process
- Study Plan Presentation and Challenge by a Mock Reviewer Panel

Skills You Will Gain:

- Viral Risk Assessment
- Cell Bank Test Programme Design
- Model Virus Selection
- Virus Inactivation Step Control
- Virus Filter Performance Evaluation
- Scale-Down Model Qualification
- Log Reduction Value Analysis
- Viral Contamination Response

Why Attend This Course:

- Leave with a Viral Clearance Strategy and Study Plan for a case monoclonal antibody process ready to adapt to your own product
- Challenge contract laboratory study designs and clearance claims before spiking runs are commissioned
- Spot the scale-down, orthogonality and worst-case gaps that reviewers question in viral safety sections
- Compare viral safety practice with peers from innovator, biosimilar, vaccine and contract manufacturing organisations

Conclusion:

Viral safety in biomanufacturing rests on three controls working together: clean source materials, proven clearance capacity and targeted product testing. The week moves from contamination routes and the viral safety triad, through cell bank and raw material testing and ICH Q5A principles, to model virus selection and the low pH, solvent/detergent, filtration and chromatography steps. It then covers scale-down qualification, spiking study design, log reduction value calculation and worst-case parameters, and closes with a Viral Clearance Strategy and Study Plan for a case monoclonal antibody process.