

Virus Clearance Course & Workshop

- DESCRIPTION:** This program covers basic theory and practical applications for the removal / inactivation of virus contamination in biopharmaceuticals and biological materials. The course format is a combination of lecture and discussion experiences. Various orthogonal methods of viral inactivation/removal will be discussed which includes chromatography, inactivation technologies, e.g., UVC, Solvent/Detergent, and Nanofiltration. Course attendees will come away with a solid background and understanding of these methodologies, terminology, risk assessment and current regulatory and industry trends.
- RATIONALE:** Cell line characterization, raw material testing and validation are core concepts for the removal / reduction of any potential viral contaminants from the manufacturing processes and drug / therapeutic product. These are necessary consideration to ensure viral removal and product safety as required by regulatory guidance and industry standards.
- TARGET AUDIENCE:** Process Development, R&D Engineers and Scientists, Quality Control and Regulatory Affairs Personnel.
- DURATION:** One Day Lecture Course with workshop session
- PREREQUISITES:** Basic understanding of life science and microbiology (helpful)
- OBJECTIVES:** At the completion of this workshop the participant will be able to:
- Gain a better understanding of terminology used.
 - Distinguish viral types, RNA-DNA, and review nomenclature.
 - Understand virus safety for biologicals, biopharmaceuticals.
 - Know methods for detecting viral contamination, PCR, CPE, TEM.
 - Understand new methods for virus inactivation / removal technologies.
 - Determine methods and robustness to achieve LRV in process.
 - Discuss current industry perspective on virus validation studies.
 - Know current regulatory guidance and industry standards and trends.
- MATERIALS:**
- A/V Equipment
 - Basic Laboratory Chemicals & Glassware
 - Virus Filtration Apparatus with pump
 - Virus Filters (20nm) + prefilter (0.2um & 0.1um) 47mm Discs
 - Personal Safety Equipment
 - Handbook of Slides