Agenda

PDA Virus Conference 2025

Tuesday, 24 June

09:00 – 09:05

Welcome and Introduction

Committee Member: Falk Klar, **PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*

09:05 – 09:15

Welcome from the Co-Chairs

Co-Chair: Chakameh Azimpour, **PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma*

Co-Chair: Sean Michael O'Donnell, **PhD**, Executive Director, *Eli Lilly and Company*

09:15 – 11:10

Opening Plenary

Viral safety of all biopharmaceutical products is at the forefront of ensuring patient safety. In this opening session of the PDA Virus Conference 2025, attendees will hear a patient's experience taking biopharmaceutical products and from a doctor who treats patients needing these critical treatments. There will also be presentations from regulators about using high throughput sequencing for viral safety testing, followed by a regulatory update from the US FDA.

Moderator: Sean Michael O'Donnell, **PhD**, Executive Director, *Eli Lilly and Company*

09:15 – 09:40

Title to be Announced

Keynote Speaker: Merete Schmiegelow

09:40 – 10:05

Update from European Pharmacopeia -Testing HTS Document

Regulatory Presenter: Johannes Bluemel, **PhD**, Head of Virus Safety Section, *Paul-Ehrlich-Institut*

10:05 – 10:30

Regulatory Updates

Regulatory Presenter: Arifa S Khan, **PhD**, Supervisory Microbiologist, DVP, OVRR, CBER, *U.S. FDA*

10:30 – 11:10

Q&A, Discussion

Moderator: Sean Michael O'Donnell, **PhD**, Executive Director, *Eli Lilly and Company*

Regulatory Panelist: Johannes Bluemel, **PhD**, Head of Virus Safety Section, *Paul-Ehrlich-Institut*

Regulatory Panelist: Arifa S Khan, **PhD**, Supervisory Microbiologist, DVP, OVRR, CBER, *U.S. FDA*

Panelist: Merete Schmiegelow

11:10 – 11:40

Networking Coffee Break, Poster Session & Exhibition

11:40 – 12:55

Session 1: Viral Safety in Manufacturing

The expanded section on platform data and prior knowledge in the new ICH Q5A (R2) guidelines provides a more detailed understanding of how such data can be leveraged in regulatory submissions for biopharmaceutical products. Much has been learned over the years, particularly in low pH inactivation and virus filtration. Continuous bioprocessing presents challenges in understanding how the virus load might change throughout the campaign. This session will focus on the application of platform and prior knowledge in case studies of manufacturing processes.

Moderator: Andy Bailey, **PhD**, CEO, *ViruSure GmbH*

11:40 – 11:55

A Case Study: Leveraging “In-House” Platform Data for Prior Knowledge Application in Low PH Viral Inactivation, Viral Reductive Filtration, and Evaluation of Resin Reuse

Presenter: Rasika Nawimanage, **PhD**, Scientist, *Teva Pharmaceuticals*

11:55 – 12:10

A Predictive Modeling Tool to Quantitate Virus Contamination Risk in Integrated Continuous Bioprocessing

Presenter: Ushma Mehta, **MS**, Senior Regulatory Expert, *MilliporeSigma*

12:10 – 12:25

Establishing Virus Filtration Design Space for Process Optimization and Utilization as Prior Knowledge: Perspectives on Filtration Characteristics and Virus Removal Performance

Presenter: Chie Hashikawa-Muto

12:25 – 12:55

Q&A, Discussion

Moderator: Andy Bailey, **PhD**, CEO, *ViruSure GmbH*

Panelist: Chie Hashikawa-Muto

Panelist: Ushma Mehta, **MS**, Senior Regulatory Expert, *MilliporeSigma*

Panelist: Rasika Nawimanage, **PhD**, Scientist, *Teva Pharmaceuticals*

12:55 – 13:10

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LIVE Guided Poster Walk

Moderator: Michael Lasse, **PhD**, Head of Product Management Filtration Consumables, *Sartorius*

13:10 – 14:10

Networking Lunch Break, Poster Session & Exhibition

14:10 – 14:25

Interactive Questionnaire Session

Moderator: David Cetlin, **MS**, Senior Director, R&D, *Cygnus Technologies*

14:10 – 15:35

Session 2: Emerging Pathogen Detection

As the biopharmaceutical industry continues to advance, the ability to rapidly detect and mitigate emerging viral threats remains a critical priority. This session will explore cutting-edge strategies for early pathogen detection, risk assessment, and control, with a focus on novel and emerging challenges. Attendees will discover the emerging global trends in novel pathogen identification, delve into the unique challenges of pathogen elimination in xenotransplantation and finally stay abreast with cutting-edge developments in virus detection methodologies. As laid forth in PDAs Technical Report 71.

Moderator: Sebastian B. Teitz, **PhD**, Senior Development Scientist, *Novo Nordisk*

14:25 – 14:40

Novel Pathogens: Global Trends and Strategies for Their Prevention and Control

Presenter: Alison Armstrong, **PhD**, Senior Director, Global Head Scientific and Regulatory Consultancy, *Merck KgAG*

14:40 – 14:55

Xenotransplantation: Elimination of Potential Pathogens from Living Organ Donors, A New Challenge

Academic Presenter: Joachim Denner, **PhD**, Head of laboratory, *Institute of Virology, Freie Universität Berlin*

14:55 – 15:05

Updates from PDA Technical Report 71 - Emerging Methods for Virus Detection

15:05 – 15:35

Q&A, Discussion

Moderator: Sebastian B. Teitz, **PhD**, Senior Development Scientist, *Novo Nordisk*

Academic Panelist: Joachim Denner, **PhD**, Head of laboratory, *Institute of Virology, Freie Universität Berlin*

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16:05 – 17:20

Session 3: Speed Talks - Virus Testing

Virus Testing of Biologics has substantially evolved over the last decade based on the technological advancement and increasing application of next generation sequencing/high throughput sequencing (NGS/HTS) for Viral Safety purposes. This Session provides both background and specific examples on how NGS/HTS have been implemented in alignment with modernized regulatory guidelines. The presenters will share their experience, key lessons-learned, and innovations regarding the development and validation of NGS/HTS in a GxP environment.

Moderator: Remo Leisi, **PhD**, Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety, *CSL*

16:05 – 16:15

Enhanced Detection of Adventitious Viruses in Biological Products Using High-Throughput Sequencing

Presenter: Song Sun, **PhD**, Unit Head of High-throughput Sequencing, *Sanofi*

16:15 – 16:25

Developing and Validating GAMP 5 Bioinformatics Software in a GMP-Regulated Environment

Presenter: Jared Richardson, **PhD**, Staff Bioinformatics Scientist, *Regeneron Pharmaceuticals*

16:25 – 16:35

Automated Virus NGS for GMP Testing: Bioinformatic Considerations & Hit Criteria

Presenter: Jesper Storm Jensen

16:35 – 16:45

10-Year Retrospective of Biological Testing Using NGS: From Past Achievements to Routine Clinical Batch Release Control

Presenter: Marc Eloit, **Prof DVM PhD**, Founder and Scientific Advisor PathoQuest, *PathoQuest*

16:45 – 17:20

Q&A, Discussion

Moderator: Remo Leisi, **PhD**, Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety, *CSL*

Panelist: Marc Eloit, **Prof DVM PhD**, Founder and Scientific Advisor PathoQuest, *PathoQuest*

Panelist: Jared Richardson, **PhD**, Staff Bioinformatics Scientist, *Regeneron Pharmaceuticals*

Panelist: Song Sun, **PhD**, Unit Head of High-throughput Sequencing, *Sanofi*

Panelist: Jesper Storm Jensen

17:20 – 22:00

End of Conference Day 1 & Networking Event

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Wednesday, 25 June

09:00 – 09:05

Welcome to Day 2

Co-Chair: Chakameh Azimpour, **PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma*

Co-Chair: Sean Michael O'Donnell, **PhD**, Executive Director, *Eli Lilly and Company*

09:05 – 10:30

Session 4: Sustainable Manufacturing

The topic of sustainable manufacturing is viewed through the optimization of the whole product lifecycle and aligns with the generation of manufactured products that use processes to minimize negative environmental impacts and conserve energy and natural resources. The presentations in this session will touch on restrictions of synthetic chemicals, Per- and polyfluoroalkyl substances (PFAS), which pose a challenge to biopharmaceutical manufacturing and directly impact PFAS raw materials including virus filtration devices, and in addition, the relevance of environmental aspects of virus care pathways will be highlighted.

Moderator: Alison Armstrong, **PhD**, Senior Director, Global Head Scientific and Regulatory Consultancy, *Merck KgAG*

09:05 – 09:25

Per- and Polyfluoroalkyl Substances (PFAS) - The Industry's Next Triton X-100? - Insights on How to Maintain and Create Regulatory Compliant Manufacturing Processes

Presenter: Fritjof Linz, **PhD**, Head of Product Management Excellence, *Sartorius Stedim Biotech GmbH*

09:25 – 09:45

Sustainability in Virus Care Pathways

Presenter: Frederik van Deurs

09:45 – 10:00

Updates from PDA Technical Report 83 Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness, and Response

Presenter: Houman Dehghani, **PhD**, Vice President, *Cabaletta Bio*

10:00 – 10:30

Q&A, Discussion

Moderator: Alison Armstrong, **PhD**, Senior Director, Global Head Scientific and Regulatory Consultancy, *Merck KgAG*

Panelist: Houman Dehghani, **PhD**, Vice President, *Cabaletta Bio*

Panelist: Fritjof Linz, **PhD**, Head of Product Management Excellence, *Sartorius Stedim Biotech GmbH*

Panelist: Frederik van Deurs

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10:30 – 11:00

Networking Coffee Break, Poster Session & Exhibition

11:00 – 12:20

Session 5: Viral Safety of ATMPs

In the dynamic landscape of Advanced Therapy Medicinal Products (ATMPs), ensuring viral safety is crucial for safeguarding patient health and adhering to regulatory standards. This session will focus on the viral safety challenges and solutions specific to the development and manufacturing of Adeno-associated virus (AAV) gene therapies. We will hear from two engaging talks on mitigating viral and TSE risks during manufacturing, and explore chromatographic techniques to enrich AAV capsids while focusing on viral safety.

Moderator: David R. Van Houte, **PhD**, Senior Manager - QC Virology, *Regeneron Pharmaceuticals*

11:00 – 11:25

Identification and Mitigation of Viral and Transmissible Spongiform Encephalopathy (TSE) Risks for the Manufacture of an Adeno-Associated Virus (AAV) Gene Therapy – A Case Study

Presenter: Denis Klochkov

11:25 – 11:50

From Full Capsid Enrichment to Virus Safety: Chromatographic Solutions for AAV Processing

Presenter: Julio Miguel Huato

11:50 – 12:20

Q&A, Discussion

Moderator: David R. Van Houte, **PhD**, Senior Manager - QC Virology, *Regeneron Pharmaceuticals*

Panelist: Julio Miguel Huato

Panelist: Denis Klochkov

12:20 – 13:20

Networking Lunch Break, Poster Session & Exhibition

13:20 – 16:30

Closing Plenary

This session will start with an insightful talk on the impact of Virus-like particle selection on determination of Residence Time Distribution Determination for Continuous Viral Inactivation Reactors, followed by an opportunity to join the discussion with distinguished virus safety experts from both industries as well as regulatory agencies for a lively discussion. Participants then have an opportunity to join interactive round table discussions around the topics of primary interest, such as experiences with validation of NGS for viral safety, use of platform knowledge, alternative strategies and continuous processing, and viral safety of ATMPs.

Moderator: Chakameh Azimpour, **PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma*

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13:20 – 13:45

Impact of Virus-like particle selection on determination of Residence Time Distribution Determination for Continuous Viral Inactivation Reactors

Regulatory Presenter: Scott Lute, **M.Sc.**, Senior Biologist, *U.S. FDA*

13:45 – 14:30

Closing Plenary Discussion

Moderator: Chakameh Azimpour, **PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma*

Regulatory Panelist: Scott Lute, **M.Sc.**, Senior Biologist, *U.S. FDA*

14:30 – 15:00

Networking Coffee Break, Poster Session & Exhibition

15:00 – 16:05

Interactive Round Table Session

16:05 – 16:10

Passport Raffle Announcement

16:10 – 16:15

Best Poster Presentation

16:15 – 16:25

Co-Chairs Conference Summary

Co-Chair: Sean Michael O'Donnell, **PhD**, Executive Director, *Eli Lilly and Company*

Co-Chair: Chakameh Azimpour, **PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma*

16:25 – 16:30

Closing Remarks & Farewell

Committee Member: Falk Klar, **PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*

16:30 – 16:30

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End of Conference