Agenda

PDA Virus Conference 2024

Wednesday, 26 June

09:00 – 09:05

Welcome and Introduction

Committee Member: Falk Klar, **PhD**, *Parenteral Drug Association*

09:05 – 09:15

Welcome from the Co-Chairs

Co-Chair: Andy Bailey, **PhD**, CEO, *ViruSure GmbH*

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

09:15 – 10:45

Opening Plenary: ICH Q5A (R2) and the Importance of Viral Safety to the Patient

Patient safety and eliminating the risk of virus contamination in biologics is at the heart of all regulations relating to virus safety. Understanding the patient perspective and the impact that these life-saving products have on patient quality of life reinforces the importance of guidelines like the ICH Q5A, as well as others relating to virus safety. The presentations in this opening plenary session set the stage for this year's PDA Virus Conference by reinforcing the importance to the industry of having a well-balanced guideline addressing the key concepts for assuring virus safety.

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

09:15 – 09:45

A Patient Perspective: The Path to Resilience: Finding Confidence in Yourself and Managing Your Condition

Keynote Speaker: Rick S., Patient Advovate, *CSL Behring*

09:45 – 10:15

Updates on ICH Q5A (R2)

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

10:15 – 10:45

Plenary Discussion

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

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

Panelist: Rick S., Patient Advovate, *CSL Behring*

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

10:45 – 11:15

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Networking Coffee Break, Poster Session & Exhibition

11:15 – 12:35

Session 1: Viral Safety of Advanced Therapies

With the advance of treatments for novel therapies, the impact on virus safety remains a core consideration. Gene therapy delivery systems have shown great promise and this session, with strong reference to adenovirus-associated virus (AAV) products, will examine platform manufacturing processes that focus on safety in upstream and downstream parameters. Also testing capabilities for the detection of replication-competent virus, again showcasing AAV, have been complex and challenging, and proposed solutions will be provided. The introduction of molecular-based technologies in viral safety testing, and long-read nanopore Next Generation Sequencing (NGS) used for the characterization of critical quality attributes for rAAV products will also be discussed.

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

11:15 – 11:30

Viral Safety Strategy for Adeno-Associated Virus Gene Therapy Products

Presenter: Nicholas DiGioia

11:30 – 11:45

The Design, Development, and Validation of Platform Methodology for Replication Competent Adeno Associated Virus

Presenter: Amy Bennett, **MS**, Manager of Virology Scientific Support Services, *Charles River Laboratories*

11:45 – 12:00

Harnessing Next-Generation Long-Read Nanopore Sequencing for Critical Quality Attribute Testing of rAAV Products in a GMP Environment

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

12:00 – 12:35

Q&A, Discussion

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

Panelist: Amy Bennett, **MS**, Manager of Virology Scientific Support Services, *Charles River Laboratories*

Panelist: Nicholas DiGioia

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

12:35 – 14:05

Networking Lunch Break & Exhibition

13:50 – 14:05

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PDA Virus Conference 2024

Guided Poster Walk

Moderator: Sebastian B. Teitz, **PhD**, Consultant, *Consultant*

13:50 – 14:05

Interactive Questionnaire Session

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

14:05 – 15:25

Session 2: Virus Testing

Conceptually, the benefits of using agnostic and highly sensitive methods for the detection of adventitious viruses have been welcome for several years. Technical, quality-assurance and regulatory hurdles have, however, not led to broad implementation across the biotechnology industry. With recent changes in the regulatory landscape, this may now change, with the ultimate goal to replace technically outdated methods still widely in use and ultimately to improve the breadth of adventitious virus detection.

Moderator: Thomas R. Kreil, **PhD**, Vice President, Global Pathogen Safety, *Takeda*

14:05 – 14:20

Temperature Check: Adoption and Challenges of NGS Implementation from the CRO Perspective

Presenter: Bradley Hasson, **MBA**, Director of Lab Operations for NGS, *Merck KGaA*

14:20 – 14:35

Approaches for Accelerated Adventitious Virus Testing and Follow-Up-Strategies for Rapid Differentiation of Replicating Viral Infections from Inert Viral Sequences in Viral Vector Vaccines and Raw Materials

Presenter: Oliver Klepsch

14:35 – 14:50

Transcriptomic NGS assay of cells: detection range and sensibility for the 71 human, porcine, and bovine rodent viruses to be detected by the MAP/RAP/HAP, 9CFR, and PCR regulatory assays

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

14:50 – 15:25

Q&A, Discussion

Moderator: Thomas R. Kreil, **PhD**, Vice President, Global Pathogen Safety, *Takeda*

Panelist: Oliver Klepsch

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

Panelist: Bradley Hasson, **MBA**, Director of Lab Operations for NGS, *Merck KGaA*

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15:25 – 15:55

Networking Coffee Break, Poster Session & Exhibition

15:55 – 17:15

Session 3: Novel Approaches and Digitization

Artificial intelligence (AI), machine learning (ML), deep learning (DL), and robotics are the latest buzzwords being applied to biologics and emerging technologies. Computer-based strategies are being developed to overcome the challenges of intensive labor in big data analysis and human bias in the interpretation of results from biological assays. Presentations in this session will show the promise of a DL model for the detection of adventitious agents and automation of infectivity assays using AI. Additionally, the use of a virus-specific PCR assay to replace infectivity assays for rapid investigations of bioreactor contamination will be presented.

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

15:55 – 16:10

A Deep-Learning Classifier of Adventitious Agents

Presenter: Tom J.B de Man, **MSc**, Head of Omics and Machine Learning R&D, *Merck KGaA*

16:10 – 16:25

Automation of Virus Detection Assays Used in Virus Clearance Studies: From Liquid Handling to the Use of Machine-learning and Artificial Intelligence in Analyzing Cytopathic Effects

Presenter: Eleonora Widmer, **PhD, MD**, Executive Director Global Pathogen Safety, *CSL Behring*

16:25 – 16:40

Adventitious Agent Testing for MMV: How Much Do We Really Know?

Presenter: Maria R. Farcet, **PhD**, Director, Cell Culture, Virus Models & Serology, *Global Pathogen Safety, Takeda*

16:40 – 17:15

Q&A, Discussion

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

Panelist: Tom J.B de Man, **MSc**, Head of Omics and Machine Learning R&D, *Merck KGaA*

Panelist: Eleonora Widmer, **PhD, MD**, Executive Director Global Pathogen Safety, *CSL Behring*

Panelist: Maria R. Farcet, **PhD**, Director, Cell Culture, Virus Models & Serology, *Global Pathogen Safety, Takeda*

17:15 – 22:00

End of Conference Day 1 & Networking Event

Agenda

PDA Virus Conference 2024

Thursday, 27 June

09:00 – 09:01

Welcome to Day 2

Co-Chair: Andy Bailey, **PhD**, CEO, *ViruSure GmbH*

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

09:02 – 10:15

Session 4: Virus Inactivation and Virus Removal

The incorporation of effective virus clearance steps represents a major pillar for ensuring virus safety of therapeutic products that are based on biologically derived materials. This session will discuss the application and contribution of virus inactivation and removal in various cases: Heat inactivation of Hepatitis E virus (HEV), which has emerged as a relevant concern for plasma-derived medicinal products; strategies for implementing effective virus filtration in continuous manufacturing; and safety considerations related to the use of animal materials in medical devices.

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

Moderator: Tomoko Hongo, **PhD**, Lead Expert, Bioprocess Division, *Asahi Kasei Medical Co., Ltd.*

09:15 – 09:30

Viral Clearance Validation of Continuous Virus Filtration: Adapting Alternate Approaches to a New Manufacturing Paradigm

Presenter: Daniel Strauss, **PhD**, Director of Research and Development, *Asahi Kasei Bioprocess America*

09:30 – 09:45

Virus Safety of Medical Devices Utilizing Animal Materials

Presenter: Ursula Lauer

10:15 – 10:45

Networking Coffee Break, Poster Session & Exhibition

10:45 – 12:00

Session 5: Next Generation Sequencing

The updated ICH Q5A (R2) promotes the adoption of Next Generation Sequencing (NGS) technologies to either supplement or replace the traditional viral safety tests. This session will explore the performances of NGS in detecting viruses across various sample types, employing different sequencing technologies and testing approaches. The speakers will present data on NGS sensitivity for virus detection and comparative data against in vivo and in vitro tests, thereby providing new insights into NGS capabilities.

Moderator: Simone Olgiati, **PhD**, Head of Innovative Sequencing & Bioinformatics Group, *Merck*

10:45 – 11:00

Evaluation of Next Generation Sequencing Performance for in vitro Detection of Viruses in Biological Products

Academic Presenter: Ken Kono, PhD, Chief, *National Institute of Health Sciences*

11:00 – 11:15

Head-to-Head Comparison of NGS with in Vivo Animal Assays and in Vitro Cell Culture Assays for Adventitious Virus Detection

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

11:15 – 11:30

High-Throughput Sequencing (HTS) Transcriptomics Analysis for the Detection of Viral Contaminants in Cells Used for Manufacturing of Biologics

Presenter: Noémie Deneyer, PhD, Molecular Biology Lead, *GSK*

11:30 – 12:00

Q&A, Discussion

Moderator: Simone Olgiati, PhD, Head of Innovative Sequencing & Bioinformatics Group, *Merck*

Panelist: Noémie Deneyer, PhD, Molecular Biology Lead, *GSK*

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

Academic Panelist: Ken Kono, PhD, Chief, *National Institute of Health Sciences*

12:00 – 13:00

Networking Lunch Break, Poster Session & Exhibition

13:00 – 13:15

Interactive Questionnaire Session

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

13:15 – 14:15

Session 6: Sustainability

In the bio/pharmaceutical sector, achieving sustainability and lowering environmental impact can present a difficult challenge when balancing corporate and environmental interests. According to The Underswell Foundation, while sustainability is a complex and urgent topic, it is also one of the biggest economic opportunities of our lifetime! This plenary will reflect on the efforts of companies to replace the Triton X-100 with environmentally friendly alternatives. Presentations will focus on eco-friendly & biodegradable alternatives used in continuous processes and identifying an alternative with similar impact on process performance & protein stability.

Moderator: Sebastian B. Teitz, PhD, Consultant, *Consultant*

13:15 – 13:30

The Development of a Sustainable Alternative Detergent to Triton X-100

Presenter: Russell van Buskirk, Senior Principal Scientist, *Amgen*

13:30 – 13:45

Eco-Friendly Detergent Inactivation and Clearance for a Hybrid-Continuous Process for Biologics Manufacturing

Presenter: Derek Pacheco, Scientist I, *Just-Evotec Biologics*

14:15 – 14:45

Networking Coffee Break, Poster Session & Exhibition

14:45 – 14:50

Passport Raffle

Moderator: Melanie Decker, *Parenteral Drug Association*

14:50 – 16:20

Closing Plenary: Regulatory Perspectives and Novel Therapies

Viral safety is required for biopharmaceutical products and is always evolving as new product types are manufactured. In this session, we will hear an update on viral safety from the FDA and hear about viral safety for xenotransplantation. The session will conclude with an expert panel of regulators and industry members who will give their perspectives on viral safety.

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

14:50 – 15:15

Center for Drug Evaluation and Research Updates on Viral Safety

Regulatory Presenter: Sarah A. Johnson, **PhD**, Senior Biologist, OPQ, CDER, *U.S. FDA*

15:15 – 15:40

Virus Safety of Xenotransplantation

Academic Presenter: Joachim Denner, **PhD**, Head of laboratory, *Institute of Virology, Free University Berlin*

15:40 – 16:20

Plenary Discussion

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

Regulatory Panelist: Sarah A. Johnson, **PhD**, Senior Biologist, OPQ, CDER, *U.S. FDA*

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

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

Academic Panelist: Joachim Denner, **PhD**, Head of laboratory, *Institute of Virology, Free University Berlin*

Panelist: Thomas R. Kreil, **PhD**, Vice President, Global Pathogen Safety, *Takeda*

16:20 – 16:35

Co-Chairs Conference Summary

Co-Chair: Andy Bailey, **PhD**, CEO, *ViruSure GmbH*

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

16:35 – 16:40

Closing Remarks & Farewell

Committee Member: Falk Klar, **PhD**, *Parenteral Drug Association*