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

10:45 – 11:15
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

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>11:15 – 11:30</td>
<td><strong>Viral Safety Strategy for Adeno-Associated Virus Gene Therapy Products</strong>&lt;br&gt;<strong>Presenter:</strong> Nicholas DiGioia</td>
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<td>11:30 – 11:45</td>
<td><strong>The Design, Development, and Validation of Platform Methodology for Replication Competent Adeno Associated Virus</strong>&lt;br&gt;<strong>Presenter:</strong> Amy Bennett, MS, Manager of Virology Scientific Support Services, Charles River Laboratories</td>
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<td>11:45 – 12:00</td>
<td><strong>Harnessing Next-Generation Long-Read Nanopore Sequencing for Critical Quality Attribute Testing of rAAV Products in a GMP Environment</strong>&lt;br&gt;<strong>Presenter:</strong> David R. Van Houte, PhD, Manager - QC Virology, Regeneron Pharmaceuticals</td>
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<td>12:00 – 12:35</td>
<td><strong>Q&amp;A, Discussion</strong>&lt;br&gt;<strong>Moderator:</strong> Alison Armstrong, PhD, Senior Director, Global Head Scientific and Regulatory Consultancy, Merck KgAG&lt;br&gt;<strong>Panelist:</strong> Amy Bennett, MS, Manager of Virology Scientific Support Services, Charles River Laboratories&lt;br&gt;<strong>Panelist:</strong> Nicholas DiGioia&lt;br&gt;<strong>Panelist:</strong> David R. Van Houte, PhD, Manager - QC Virology, Regeneron Pharmaceuticals</td>
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<td>12:35 – 14:05</td>
<td>Networking Lunch Break &amp; Exhibition</td>
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</tbody>
</table>
Agenda
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
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

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<tr>
<th>Time</th>
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| 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 |
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: María 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:** María R. Farcet, PhD, Director, Cell Culture, Virus Models & Serology, Global Pathogen Safety, Takeda |

17:15 – 22:00
End of Conference Day 1 & Networking Event
### 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.*

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<td>09:15 – 09:30</td>
<td>Viral Clearance Validation of Continuous Virus Filtration: Adapting Alternate Approaches to a New Manufacturing Paradigm</td>
<td>Daniel Strauss, PhD, Director of Research and Development, <em>Asahi Kasei Bioprocess America</em></td>
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<td>09:30 – 09:45</td>
<td>Virus Safety of Medical Devices Utilizing Animal Materials</td>
<td>Ursula Lauer</td>
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#### 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*

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#### PDA Virus Conference 2024

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<tr>
<td>11:00</td>
<td>Evaluation of Next Generation Sequencing Performance for in vitro Detection of Viruses in Biological Products</td>
<td><strong>Academic Presenter:</strong> Ken Kono, PhD, Chief, National Institute of Health Sciences</td>
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<td>11:00 – 11:15</td>
<td>Head-to-Head Comparison of NGS with in Vivo Animal Assays and in Vitro Cell Culture Assays for Adventitious Virus Detection</td>
<td><strong>Regulatory Presenter:</strong> Arifa S Khan, PhD, Supervisory Microbiologist, DVP, OVRR, CBER, U.S. FDA</td>
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<td>11:15 – 11:30</td>
<td>High-Throughput Sequencing (HTS) Transcriptomics Analysis for the Detection of Viral Contaminants in Cells Used for Manufacturing of Biologics</td>
<td><strong>Presenter:</strong> Noémie Deneyer, PhD, Molecular Biology Lead, GSK</td>
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<td>Session 6: Sustainability</td>
<td><strong>Moderator:</strong> Sebastian B. Teitz, PhD, Consultant</td>
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**Academic Panelist:** Ken Kono, PhD, Chief, National Institute of Health Sciences

#### 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
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<td>13:15</td>
<td>The Development of a Sustainable Alternative Detergent to Triton X-100</td>
<td>Russell van Buskirk, Amgen</td>
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<td>13:30</td>
<td>Eco-Friendly Detergent Inactivation and Clearance for a Hybrid-Continuous Process for Biologics Manufacturing</td>
<td>Derek Pacheco, Just-Evotec Biologics</td>
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<td>14:45</td>
<td>Passport Raffle</td>
<td>Melanie Decker, Parenteral Drug Association</td>
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<td>14:50</td>
<td>Closing Plenary: Regulatory Perspectives and Novel Therapies</td>
<td>Sean Michael O'Donnell, Eli Lilly and Company</td>
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<td>15:50</td>
<td>Center for Drug Evaluation and Research Updates on Viral Safety</td>
<td>Sarah A. Johnson, Senior Biologist, OPQ, CDER, U.S. FDA</td>
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<td>15:15</td>
<td>Viral Safety of Xenotransplantation</td>
<td>Joachim Denner, Institute of Virology, Free University Berlin</td>
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PDA Virus Conference 2024

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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