2019 PDA Virus Safety Forum  
Next Generation Strategies for Viral Risk Mitigation  
May 8, 2019 | Hilton Long Beach | Long Beach, CA

WEDNESDAY, MAY 8

7:15 a.m. – 8:45 a.m. | Continental Breakfast

7:30 a.m. – 8:30 a.m. | Advanced Virus Detection Interest Group Breakfast Session  
(open to all attendees)

The Advanced Virus Detection Interest Group (AVDIG) is comprised of experts representing industry, academia, government agencies, and regulatory authorities who discuss the current thinking and plan efforts regarding applications of next generation sequencing for adventitious virus detection in biologics. The AVDIG provides a forum for informal scientific discussions, knowledge exchange, and developing collaborative studies aimed at standardization of next generation sequencing technologies for adventitious virus detection in biologics. The group has focused on best practices for sample selection and processing, development of reference materials (model viruses and databases), optimization of bioinformatics pipelines, and designing follow-up strategies. The session will highlight the IGs progress, achievements, and ongoing projects followed by audience participation for Q&A.

Moderator: Arifa S. Khan, PhD, Supervisory Microbiologist, CBER, FDA

7:30 a.m. | Highlight of Interest Group Activities and Accomplishments plus Q&A Discussion

Arifa S. Khan, PhD, Supervisory Microbiologist, CBER, FDA  
Keisuke Yusa, PhD, Senior Researcher, Division of Cell-Based Therapeutic Products, National Institute of Health Sciences (NIHS)  
Dominick Vacante, PhD, Scientific Director, Janssen R&D, LLC

8:45 a.m. – 10:30 a.m. | P1: Virus Testing and Detection: Conventional Assays and New Technologies

Strategies to mitigate risk of adventitious viruses in biologics include: using qualified raw materials; incorporating steps during the manufacturing for viral clearance; and extensive testing at various steps in the manufacturing process with the greatest potential for detection of contamination. Testing is aimed at detection of both known and unknown viruses. Broad virus detection is particularly important for safety of live products, since their manufacturing cannot generally include steps for viral inactivation and removal. Although the conventional assays have generally been effective for demonstrating absence of adventitious viruses, they are not sufficiently broad to detect known, unexpected viruses, and viruses that are distant to known viruses or novel viruses. This session will present perspectives on using conventional assays and next generation sequencing technologies for adventitious virus detection in biologics.

Moderator: Dominick Vacante, PhD, Scientific Director, Janssen R&D, LLC

8:45 a.m. | Welcome and Opening Remarks from Conference Co-Chair

Brian J. Hawkins, PhD, Chief Technology Officer, Pluristem, Inc.

9:00 a.m. | High-Throughput Sequencing for Adventitious Virus Detection in Biologics

Arifa S. Khan, PhD, Supervisory Microbiologist, CBER, FDA

9:25 a.m. | Adventitious Virus Detection by Next Generation Sequencing of Newly Synthesized RNAs (REPLI-VIR): Unambiguous Differentiation of Cell Infection from Carryover of Viral Nucleic Acids

Marc Eloit, PhD, Founder and Scientific Advisor, PathoQuest and Head of Pathogen Discovery Laboratory, Institut Pasteur

9:50 a.m. | Detection of Viral Contamination in Cell Culture by Targeted Amplicon Sequencing Using Automated Next Generation Sequencing Workflow

Elena V. Bolchakova, PhD, Senior Staff Scientist, Thermo Fisher Scientific and Pia N. Darker, MSc, Senior Product Manager, Thermo Fisher Scientific

10:15 a.m. | Questions and Answers/Discussion

10:30 a.m. – 11:15 a.m. | Refreshment Break and Poster Presentations in Exhibit Area

<table>
<thead>
<tr>
<th>Poster Presentations</th>
<th>The following posters will be presented during today’s refreshment breaks</th>
</tr>
</thead>
</table>
| 1.                  | Considerations for Validating Virus Filtration in Continuous Bioprocessing Applications  
                      Ross A. Turmell, Senior Scientist, Pall Corporation |
| 2.                  | Alternative Detergents for Viral Inactivation  
                      Gabriella T. Perell, PhD, Postdoctoral Process Development Fellow, Amgen |
                      Afshin Sohrabi, PhD, Head Molecular R&D, MilliporeSigma |
| 4.                  | Virus Removal by Filtration: Comparison of Batch and Continuous Operation  
                      Susan Martin, Product Specialist: Viral Clearance, Sartorius Stedim Biotech |
| 5.                  | Applying a Next Generation Sequencing Workflow to Accelerate Biopharmaceutical Manufacturing Processes and Improve Safety  
                      Marcell Veidner, Business Development Manager, Genedata USA |
## 2019 PDA Virus Safety Forum

*Next Generation Strategies for Viral Risk Mitigation*

**May 8, 2019 | Hilton Long Beach | Long Beach, CA**

### WEDNESDAY, MAY 8, CONTINUED

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
</table>
| 11:15 a.m. – 12:45 p.m. | P2: Viral Mitigation: Critical Evaluation of Current Practice  
Viruses are the most abundant class of biological entity on Earth. Did you know that your genome is part viral, and that you are persistently infected with at least two viruses as you read this? Viral contamination in pharma is reality, illustrated by numerous high-profile events. Prevention is governed by the robustness of viral mitigation strategies, and the viral awareness of the people involved. Within this session, presenters will share case study experiences of their companies’ approach to the control of viral contamination, in terms of:  
• Prevention assumptions drawn from the control strategy  
• Critical evaluation of the risk mitigation  
• Identification of remaining risks  
• Strategies for addressing remaining risks  
Moderator: Veronica L. Fowler, PhD, Senior Virologist, Merck & Co., Inc. |
| 11:15 a.m. | Quality by Design: Rapid Alternatives for an Animal-Free Biosafety Testing Strategy  
Sarah E. Sheridan, PhD, Principal Scientist, MilliporeSigma |
| 11:40 a.m. | Best Practices for Viral Disinfection Studies in GMP Manufacturing Facilities  
Lorenzo Achenza, MS, Senior Scientist, MSD |
| 12:05 p.m. | Assessment of Viral Inactivation of Cleaned Surfaces  
Paul Lopolito, Technical Services Senior Manager, STERIS Corporation |
| 12:15 p.m. | Questions and Answers/Discussion |
| 12:45 p.m. – 1:45 p.m. | Networking Lunch |
| 1:45 p.m. – 3:15 p.m. | P3: Virus Clearance: The Central Pillar of Pathogen Safety  
Impactful and tragic pathogen contamination events in the past led us, the biopharmaceutical industry, into embracing a comprehensive virus safety strategy, commonly referred to as the “safety tripod” consisting of selecting, testing, and clearance. The clearance pillar alone typically contributes an estimated 10,000-fold increase in safety assurance as compared to the pillars of selecting and testing combined. This session will investigate the state-of-the-art technologies and the future of protecting patients from virus transmission through sound virus clearance concepts.  
Moderator: Sebastian B. Teitz, PhD, Scientific Coordinator, ASAHI Kasei Bioprocess |
| 1:45 p.m. | Model Viruses in Viral Clearance Studies: Real Models?  
Horst Ruppach, PhD, Director Pathogen Safety, Charles River Laboratories |
| 2:05 p.m. | High pH Inactivation of Enveloped Viruses in an Fc-Fusion Molecule Prone to Aggregation at Low pH  
Eric R. Weiss, PhD, Senior Scientist, MilliporeSigma |
| 2:25 p.m. | From “Batch Mode” to “Continuous” Bioprocessing: How the Virus Filter Fits In  
Julie Kozaii, PhD, Scientist, Asahi Kasei Bioprocess |
| 2:45 p.m. | Questions and Answers/Discussion |
| 3:15 p.m. – 4:00 p.m. | Refreshment Break and Poster Presentations in Exhibit Area |
| 4:00 p.m. – 5:15 p.m. | P4: Think Tank: Practical Considerations and Applications for Viral Safety Challenges  
In this session, panel members and the audience will engage in discussions on advancements in virus detection technologies and methods for viral inactivation and removal, and their implementation and applications to mitigate risk of virus contamination in different biological products. Technologies to prevent potential virus contaminants entering the process stream will also be discussed.  
Moderator: Brian J. Hawkins, PhD, Chief Technology Officer, Pluristyx, Inc. |
| 4:00 p.m. | Panel Discussion with Session Moderators  
Veronica L. Fowler, PhD, Senior Virologist, Merck & Co., Inc.  
Arifa S. Khan, PhD, Supervisory Microbiologist, CBER, FDA  
Sebastian B. Teitz, PhD, Scientific Coordinator, ASAHI Kasei Bioprocess  
Dominick Vacante, PhD, Scientific Director, Janssen R&D, LLC |
| 5:00 p.m. | Closing Remarks from Conference Co-Chair  
Brian J. Hawkins, PhD, Chief Technology Officer, Pluristyx, Inc. |