2022 PDA VIRUS Conference

Changing Landscape of Viral Safety - Existing and Advanced Technologies

Brussels/Belgium

20-21 June 2022

Monday, 20 June 2022		**09:00 – 17:30**
09:00	Welcome and Introduction	Falk Klar, *PDA Europe*
09:10	Welcome from the Chairs	Alison Armstrong, *Merck KGaA* Thomas R. Kreil, *Takeda*
09:20	**Keynote:** New Methods to Ensure Virus Safety in the Production of Biologics	David E Onions, *Norcliffe Capital*
Opening Plenary: Updates from the Regulatory Landscape		**Moderators:** Alison Armstrong, *Merck KGaA* Thomas R. Kreil, *Takeda*
Patient safety is a shared priority for the biopharmaceutical industry as well as regulatory bodies. To ensure adequate virus safety margins of medicinal products, collaboration rather than competition is often chosen by the parties involved, to make the most effective use of the totality of available data and experiences. Two notable collaborative studies and their results will be presented and discussed.		
09:45	Update on the revision of Guideline ICH Q5A	Johannes Blümel, *Paul-Ehrlich-Institut*
10:10	Regulatory Update of Viral Safety	Scott Lute, *U.S. FDA*
10:35	**Q&A, Discussion**	
11:05	**Coffee Break, Poster Session & Exhibition**	
Session 1: Virus Filtration		**Moderator:** Sean O'Donnell, *Eli Lilly*
Viral Filtration is a very robust method for the removal of a broad host range of viruses solely based on size. Several factors can affect the removal of the virus through viral filtration, which includes volumetric throughput, start, stop of flow, and pressure. This session will discuss the effect of virus load on virus breakthrough and the effects of filter fouling on virus breakthrough.		

11:35	Visualizing Protein Fouling and its Impact on Parvovirus Retention Within Distinct Filter Membrane Morphologies	Remo Leisi, *CSL Behring*
12:00	A New Reliable Approach to Viral Clearance Study Design from the Amount of Virus Load	Tomoko Hongo, *Asahi Kasei*
12:25	**Q&A, Discussion**	
12:55	**Lunch Break, Poster Session & Exhibition**	
Session 2: Preparedness of Biotechnology Industry against Pandemics		**Moderator:** Johannes Blümel, *Paul-Ehrlich-Institut*
New pandemics pose a threat, not only to the viral safety of biological products but also to maintaining production. Lessons learned during the COVID-19 pandemic on supply issues will be explained. Beyond coronaviruses, the potential of other viruses to switch host species and potential consequences to humans and biomedical products will be discussed.		
13:55	Zoonotic Viruses and Humans: Emerging, Pandemic, and Seasonal Patterns of Circulation	Thomas R. Kreil, *Takeda*
14:20	Dual Sourcing of Raw Materials during the Pandemic	John Fisher, *Genentech/Roche*
14:45	**Q&A, Discussion**	
15:15	**Coffee Break, Poster Session & Exhibition**	
Session 3: Next Generation Sequencing (NGS) and Virus Detection		**Moderator**: Jean-Pol Cassart, *GSK*
The capabilities of NGS for the detection of known and novel viruses have advanced the use of this technology as an alternative for supplementing or replacing the currently used *in vivo* and *in vitro* adventitious virus detection assays. This session will present studies demonstrating NGS virus detection in biological materials and virus discovery in support of NGS use for broad adventitious virus detection.		
15:45	Identification of an Epizootic Hemorrhagic Disease Virus (EHDV) Contamination Event in a Biopharmaceutical Product	Andy Bailey, *ViruSure*

	using a Combination of Adventitious agent Testing and Next Generation Sequencing	
16:10	Use of Next Generation Sequencing Technology for Broad Virus Screening in Biologically Derived Samples: A Case Study with SARS-CoV-2 Challenge Virus	Bradley Hasson, *Merck KGaA*
16:35	NGS Contribution to Virus Discovery: Bat Coronaviruses related to SARS-CoV-2 and Infectious for Human Cells	Marc Eloit, *Institut Pasteur*
17:00	**Q&A, Discussion**	
17:30	**End of Conference Day 1 & Networking Event**	

Tuesday, 21 June 2022 — 08:00 – 16:10

Interest Group Morning Session: Advanced Virus Detection Technologies Interest Group (AVDTIG) Session- open for the audience-		Moderator: Arifa Khan, *U.S. FDA*
The AVDTIG is a multidisciplinary international effort with a focus on developing standards and conducting collaborative studies for the qualification of NGS technologies for adventitious virus detection in biologics. The session will provide background, ongoing activities, and achievements of the Interest Group, and the status of ongoing collaborative studies for evaluating virus detection using short-read and long-read NGS technologies. The session will close with audience Q&A and discussion.		
08:00	Updates on NGS Activities and Achievements in AVDTIG	Jean-Pol Cassart, *GSK*
08:30	**Q&A, Discussion**	
Session 4: Virus Inactivation		**Moderator:** Andy Bailey, *ViruSure*
Virus inactivation has and continues to play an important role in ensuring the virus safety of biological products. The mechanisms of inactivation and conditions for ensuring robust inactivation via detergent or low pH are well understood, but new challenges arising from a reduced dependency on the detergent Triton X-100		

or with the implementation of low pH in a continuous manufacturing environment require new approaches. This session will provide a discussion forum for how these challenges can be met using actual case studies.		
09:00	Detergent-based Virus Inactivation: Development and Evaluation of an Alternative for Triton X-100	Johanna Kindermann, *Takeda*
09:20	Identification of an Environmentally friendly Detergent as a Replacement for Triton X-100 in Virus Inactivation	Sean O'Donnell, *Eli Lilly*
09:40	Transitioning Low pH Mediated Viral Inactivation in Bioprocessing from Batch to Continuous Mode	Corinne Miller, *MilliporeSigma*
10:00	**Q&A, Discussion**	
10:30	**Coffee Break, Poster Session & Exhibition**	
Session 5: Viral Clearance		**Moderator:** Sebastian Teitz, *Asahi Kasei*
Within the concept that is commonly referred to as the "Virus Safety Tripod of Biopharmaceuticals" the pillar of Virus Clearance contributes by far the largest proportion in risk reduction to the biopharmaceutical product. This session will explore the systematic use of prior knowledge for improved & successful virus validation programs, simplified & more efficient Hepatitis E Virus (HEV) clearance studies as well as new insights into the mechanistic of low pH inactivation.		
11:00	A Database for Virus Clearance Data for Improved Virus Validation Programs	Moritz Bennecke, *Genentech*
11:20	Efficient Hepatitis E Virus Production in Tissue Culture and its Application in Inactivation studies	Daniel Todt, *Ruhr Uni Bochum*
11:40	Characterizing a Novel Parameter Affecting Low pH Viral Inactivation	Jena Daya, *Regeneron*
12:10	**Q&A, Discussion**	
12:40	**Lunch Break, Poster Session & Exhibition**	

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Closing Plenary: Industry Forums		**Moderators:** Alison Armstrong, *Merck KGaA* Thomas R. Kreil, *Takeda*
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13:40	Interactive questionnaire	
13:50	Update on PDA's Technical Report #41 on Virus Filtration	Sebastian Teitz, *Asahi Kasei*
14:05	**Coffee Break, Poster Session & Exhibition**	
14:35	Assessing Virus Cross-Contamination Risk between Two Simultaneous Processes in an Open Biomanufacturing Facility	Paul Barone, *Massachusetts Institute of Technology*
15:00	Panel Discussion with Regulatory and Industry Speakers	**Moderators:** Alison Armstrong, *Merck KGaA* Thomas R. Kreil, *Takeda*
15:45	**Summary by the Chairs**	Alison Armstrong, *Merck KGaA* Thomas R. Kreil, *Takeda*
16:00	**Closing Remarks & Farewell**	Falk Klar, *PDA Europe*
16:10	**End of Conference**	

The agenda is subject to change without notice