2022 PDA

VIRUS CONFERENCE

CHANGING LANDSCAPE OF VIRAL SAFETY - EXISTING AND ADVANCED TECHNOLOGIES

pda.org/EU/Virus2022

20-21 JUNE 2022
BRUSSELS, BELGIUM
EXHIBITION: 20-21 JUNE

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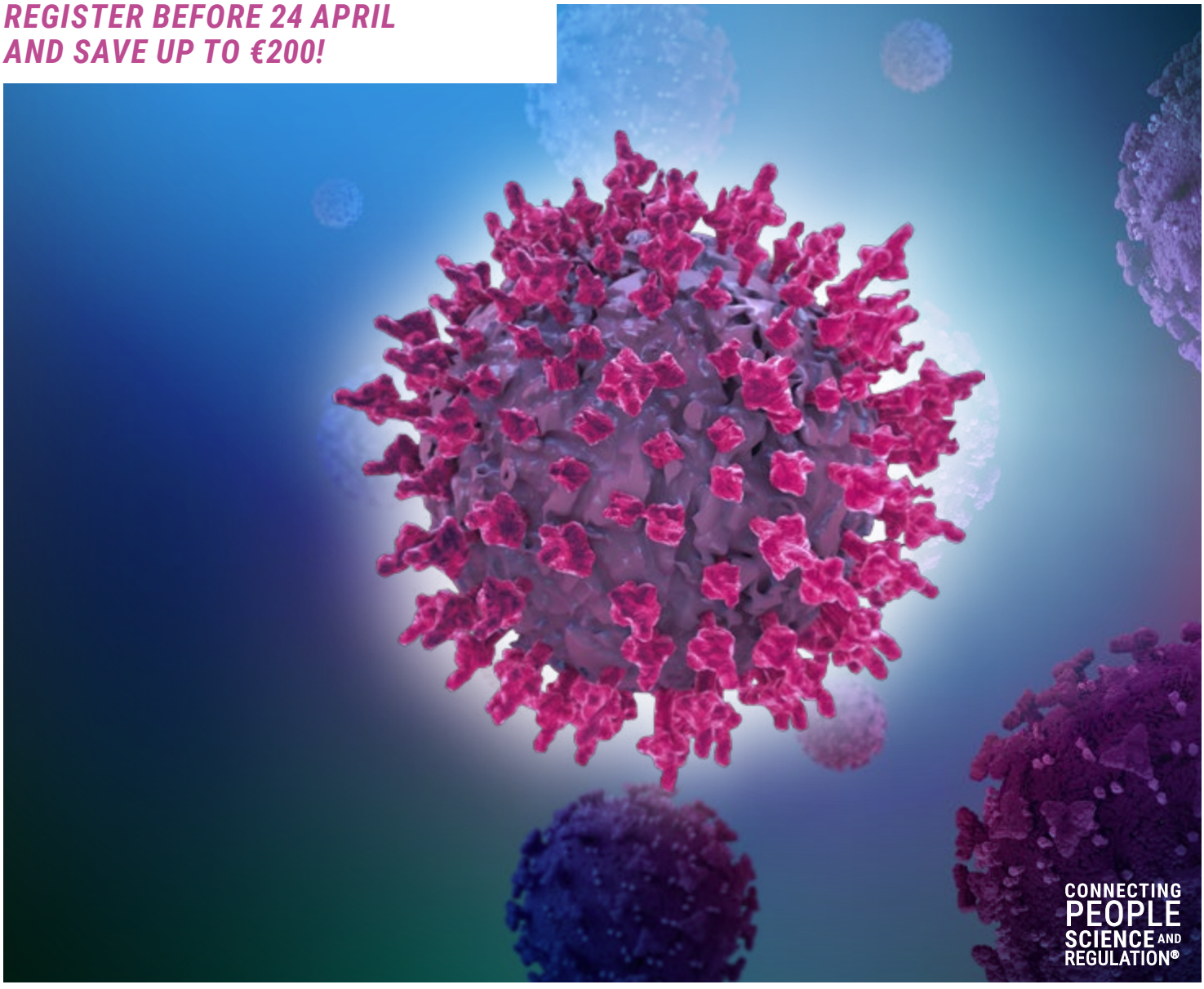

WELCOME FROM THE CHAIRS

Dear Colleagues,

On behalf of the Scientific Program Planning Committee and PDA, we would be glad to see you at the Virus Conference to take place in Brussels, Belgium.

This global meeting is organized in close collaboration with an excellent Scientific Program Planning Committee including European and U.S. FDA regulators, industry experts, supplier specialists, and dedicated PDA Europe support.

The overall program is designed to provide an update on regulatory expectations and the scientific framework around the virus safety of plasma-derived and biotechnology medicinal products, as well as particularly innovative cell- and gene therapies.

Similar to earlier events in this long-standing series, current and newly emerging viral threats, viral safety considerations around the selection of low-risk starting materials, virus detection and identification methods and strategies, and the design and validation of virus inactivation and removal processes will be key topics for discussion. In addition, intensified continuous manufacturing processes and their potential impact on facility design and viral safety will also be considered.

After a sequence of online-only events, forced by the emergence of SARS- CoV-2, the PDA Virus Conference will provide attendees the unique opportunity to re-gather in person for interactive discussions and benchmarking, as well as to reinvigorate social interactions. A discussion forum that allows direct interaction between industry and regulators will continue to support the wider industry and improve the current understanding and acceptance of new technologies, highlight new and emerging viral risks, and explain novel regulatory approaches.

Panel discussions and ample networking opportunities will complement an impressive scientific program and make it a worthwhile and well-rounded experience for you.

We look forward to seeing you!

Sincerely,
The Chairs

Alison Armstrong,
Merck KGaA

Thomas R. Kreil,
Takeda

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Alison Armstrong, *Merck KGaA, Chair*
Thomas R. Kreil, *Takeda, Chair*
Andy Bailey, *ViruSure*
Johannes Blümel, *Paul-Ehrlich-Institut*
Qi Chen, *Genentech/Roche*
Arifa S. Khan, *U.S. FDA*
Sean O'Donnell, *Eli Lilly & Company*
Mehran Rafigh, *Sartorius Stedim*
Sebastian Teitz, *Asahi Kasei*
Josh Eaton, *PDA*
Falk Klar, *PDA*
Stefanie Nebelin, *PDA Manager Programs & Events*

WELCOME TO VIRUS CONFERENCE

COVID-19 PERSONAL PRECAUTIONARY MEASURES

PDA is committed to deliver safe and secure in-person events. In conjunction with the venue and vendors supporting our event, PDA strictly adheres to all national, provincial and local government regulations.

CONFERENCE AGENDA

05. Apr 2022

MONDAY, 20 JUNE 2022 — 09:00 – 17:30

09:00	**Welcome and Introduction**	Falk Klar, *PDA Europe*
	Welcome from the Chairs	Alison Armstrong, *Merck KGaA* Thomas R. Kreil, *Takeda*
	Keynote: **New Methods to Ensure Virus Safety in the Production of Biologics**	*Norcliffe Partners*

OPENING PLENARY: Updates from the Regulatory Landscape

Moderators: **Alison Armstrong,** *Merck KGaA*
Thomas R. Kreil, *Takeda*

Recent advances in biomanufacturing practices have supported the accelerated growth in the biopharmaceutical industry. Therapeutics manufactured using cell lines of human and animal origin continue to be at risk of viral contamination, and thus biosafety strategies are a key consideration. With recent advances in science and manufacturing systems, ICHQ5A (R2) is undergoing revision to include novel therapies, address updated detection technologies and advise on manufacturing paradigms and modified viral clearance applications. Orthogonal approaches to mitigate risk are a regulatory expectation, and real-world data on viral clearance unit operations support the design and implementation of state-of-the-art biotechnology manufacturing processes.

	Update on the revision of Guideline ICHQ5A	Johannes Blümel, *PEI*
	Regulatory Update of Viral Safety	*U.S. FDA*
	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.

	Visualizing Protein Fouling and its Impact on Parvovirus Retention Within Distinct Filter Membrane Morphologies	*CSL Behring*
	A New Reliable Approach to Viral Clearance Study Design from the Amount of Virus Load	*Asahi-Kasei*
	Q&A, Discussion	
12:55	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	

SESSION 2: Preparedness of Biotechnology Industry against Pandemics

Moderator: **Johannes Blümel,** *PEI*

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.

	Zoonotic Viruses and Humans: **Emerging, Pandemic, and Seasonal Patterns of Circulation**	Thomas R. Kreil, *Takeda*
	Dual Sourcing of Raw Materials during the Pandemic	*Genentech/Roche*
	Q&A, Discussion	
15:15	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

SESSION 3: Next Generation Sequencing 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.

	Identification of an EHDV Contamination Event in a Biopharmaceutical Product Using a Combination of Adventitious Agent Testing and Next Generation Sequencing	Andy Bailey, *ViruSure*
	Use of Next Generation Sequencing Technology for Broad Virus Screening in Biologically Derived Samples: A Case Study with SARS-CoV-2 Challenge Virus	*Merck KGaA*
	NGS Contribution to Virus Discovery: Bat Coronaviruses related to SARS-CoV-2 and Infectious for Human Cells	*Institut Pasteur*
	Q&A, Discussion	
17:30	**END OF CONFERENCE DAY 1 & NETWORKING EVENT**	

CONFERENCE AGENDA

TUESDAY, 21 JUNE 2022 — 08:00 – 16:30

08:00 **INTEREST GROUP MORNING SESSION: Advanced Virus Detection Technologies IG (AVDTIG) Session**

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 IG, 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.

	Updates on NGS Activities and Achievements in AVDTIG	*GSK*
	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.

	Detergent-based Virus Inactivation: Development and Evaluation of an Alternative for Triton X-100	*Takeda*
	Identification of an Environmentally friendly Detergent as a Replacement for Triton X-100 in Virus Inactivation	Sean O'Donnell, *Eli Lilly*
	Transitioning Low pH Mediated Viral Inactivation in Bioprocessing from Batch to Continuous Mode	*MillporeSigma*
	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 HEV clearance studies as well as new insights into the mechanistic of low pH inactivation.

	A Database for Virus Clearance Data for Improved Virus Validation Programs	*Genentech*
	Efficient HEV Production in Tissue Culture and its Application in Inactivation studies	*Ruhr Uni Bochum*
	Characterizing a Novel Parameter Affecting Low pH Viral Inactivation	*Regeneron*
	Q&A, Discussion	

12:40 **LUNCH BREAK, POSTER SESSION & EXHIBITION**

CLOSING PLENARY: Industry Forums

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 most effective use of the totality of available data and experiences. Two notable collaborative studies and their results will be presented and discussed.

	Interactive Questionnaire	
	Update on PDA's Technical Report #41 on Virus Filtration	*Invited Speaker*
14:05	**Coffee Break, Poster Session & Exhibition**	
	MIT CAACB Risk Assessment Case Study: Assessing Virus Cross-Contamination Risk between Two Simultaneous Processes in an Open Biomanufacturing Facility	*Massachusetts Institute of Technology*
	Panel Discussion	*Moderators:* Alison Armstrong, *Merck KGaA* Thomas R. Kreil, *Takeda*
	Summary by the Chairs	Alison Armstrong, *Merck KGaA* Thomas R. Kreil, *Takeda*
	Closing Remarks & Farewell	Falk Klar, *PDA Europe*
16:15	**END OF CONFERENCE**	

The agenda is subject to change without notice

VENUE

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SPECIAL REQUIREMENTS

If you require special assistance to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to info@pda.org.

PDA EUROPE

UPCOMING CONFERENCES AND EVENTS

FOR FURTHER INFORMATION
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2022

05. Apr 2022

26-27 APR 2022	2022 PDA Visual Inspection Forum	Berlin, Germany
16-17 MAY 2022	2022 PDA Medical Devices and Connected Health Conference	Dublin, Ireland
16-17 MAY 2022	2022 PDA Robotics and Automation Conference	Dublin, Ireland
18-19 MAY 2022	2022 PDA Annex 1 Workshop	Dublin, Ireland
02-03 JUN 2022	2022 PDA Parenteral Packaging Conference	Basel, Switzerland
20-21 JUN 2022	2022 PDA Virus Conference	Brussels, Belgium
22-23 JUN 2022	2022 PDA Advanced Therapy Medicinal Products Conference	Brussels, Belgium
20-21 SEP 2022	2022 PDA BioManufacturing Conference	Amsterdam, The Netherlands
22-23 SEP 2022	2022 PDA Annex 1 Workshop	Amsterdam, The Netherlands
05-06 OCT 2022	2022 PDA Quality and Regulations Conference	Amsterdam, The Netherlands