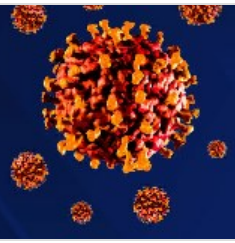
PDA Virus Conference 2026

Agenda



Monday, 22 June

CEST Daylight Time (UTC +2:00)

09:00 – 09:05	**Welcome and Introduction** **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*
09:05 – 09:15	**Welcome from the Co-Chairs** **Co-Chair: Chakameh Azimpour PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma* **Co-Chair: Remo Leisi PhD** Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety *CSL*
09:15 – 11:10	**Opening Session** **Moderator: Remo Leisi PhD**, Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety, *CSL*

09:15 – 09:40	**Title to be Announced**
09:40 – 10:05	**Title to be Announced**
10:05 – 10:30	**Title to be Announced**
10:30 – 11:10	**Q&A, Discussion** • **Moderator: Remo Leisi PhD**, Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety, *CSL*

11:10 – 11:40	**Networking Coffee Break, Poster Session & Exhibition**
11:40 – 12:55	**Session 1: Intensification of Virus Filtration** Virus filtration is considered one of the most robust unit operations, reliably contributing to effective virus clearance, and is critical to ensure patient safety during biopharmaceutical manufacturing. Although being extensively characterized throughout the last two decades, advanced manufacturing designs and challenging process conditions require continued reevaluation of process setups and the effectiveness of virus removal. This session will focus on how advanced operational modes and new process designs can enable effective virus-retentive filtration when applying intensified and continuous bioprocessing setups. **Moderator: Michael Lasse PhD**, Head of Product Management Filtration Consumables, *Sartorius*

11:40 – 11:55	**Versatile virus filtration approaches for Continuous processing using filtrate recycling** • **Presenter: Kakolie G. Banerjee PhD**, R&D Manager, Virology, *MilliporeSigma*
11:55 – 12:10	**Enabling Intensification of Large-Scale mAb Production by Increasing Virus Filter Flux and Throughput** • **Presenter: Sean Michael O'Donnell PhD**, Executive Director, *Eli Lilly and Company*
12:10 – 12:25	**Updates on Technical Report No.41, Virus Filtration** • **Presenter: John Fisher** , Senior Principal Engineer, *Genentech Inc., a Member of the Roche Group*

	12:25 – 12:55	**Q&A, Discussion** • **Moderator: Michael Lasse PhD**, Head of Product Management Filtration Consumables, *Sartorius*
12:55 – 13:20	**LIVE Guided Poster Walk**	
13:20 – 14:15	**Networking Lunch Break, Poster Session & Exhibition**	
14:15 – 15:35	**Session 2: Speed Talks - New Ways of Virus Inactivation** Advances in viral safety technologies continue to reshape biopharmaceutical manufacturing, particularly as intensified and continuous processing strategies gain traction. Novel studies in continuous viral inactivation, the emergence of tunable and environmentally friendly alternatives to Triton X-100, and the development of compliant detergent treatments for low-pH-sensitive therapeutic proteins collectively demonstrate how evolving process needs demand fresh approaches to robust virus mitigation. At the same time, innovative platforms such as low-energy electron irradiation are redefining the boundaries of next-generation viral clearance. This session will highlight how these diverse technologies can be integrated into modern bioprocess designs, ensuring reliable, effective viral safety across an increasingly complex manufacturing landscape. **Moderator: David Cetlin MS**, Senior Director, R&D, *Cygnus Technologies*	
	14:15 – 14:25	**Interactive Session** • **Moderator: David Cetlin MS**, Senior Director, R&D, *Cygnus Technologies*
	14:25 – 14:35	**Ensuring Viral Safety in Continuous Processing: Lessons learned from a Novel Inactivation Study** • **Presenter: Lisa Lipski M. Sc.**, Scientist, *Sartorius*
	14:35 – 14:45	**A Tunable Green Alternative to Triton X-100** • **Presenter: Kathryn Messina PhD**, Staff Scientist, *Ashland*
	14:45 – 14:55	**Boosting Viral Safety With Compliant Detergent Treatment for Low pH-Sensitive Therapeutic Proteins** • **Presenter: Dominik Georg Sauer Dr.**, Senior Expert Science & Technology DSP, *Novartis TRD Biologics*
	14:55 – 15:05	**Next-Generation Viral Clearance with Low-Energy Electron Irradiation** • **Presenter: Daniel Becker** , ,
	15:05 – 15:35	**Q&A, Discussion**
15:35 – 16:05	**Networking Coffee Break, Poster Session & Exhibition**	
16:05 – 17:20	**Session 3: Advanced Adventitious Virus Detection** This session explores state-of-the-art applications of next-generation sequencing (NGS) for detecting adventitious agents in biopharmaceutical products and manufacturing processes, setting the scientific and operational context for modern viral safety testing. Presentations will compare metagenomic, targeted, and hybrid NGS approaches using real-world contamination case studies and bioinformatics analyses, highlighting performance trade-offs, workflow considerations, and decision points for laboratory adoption. Attendees will gain practical guidance on assay design, controls, validation, and bioinformatics quality control, along with strategies to integrate NGS into existing testing programs. **Moderator: David R. Van Houte PhD**, Senior Manager - QC Virology, *Regeneron Pharmaceuticals*	
	16:05 – 16:20	**From RNA to Results in 26 Hours: A Nanopore-based NGS Workflow for Comprehensive Adventitious Virus Testing** • **Presenter: Michael Karbiener PhD**, Head of Virological Method and Assay Development, *Global Pathogen Safety / Takeda*

	16:20 – 16:35	**Easing the Burden of Bioinformatics Analysis Using Long-Read NGS Technologies** • **Presenter: Andy Bailey PhD**, CSO, *ViruSure GmbH*
	16:35 – 16:50	**Evaluation of Viromic, Transcriptomic, and Genomic NGS Methods for Viral Safety Testing Mimicking a Historical Live Vaccine Circovirus Contamination Event** • **Presenter: Marc Eloit Prof DVM PhD**, Founder and Scientific Advisor PathoQuest, *PathoQuest*
	16:50 – 17:20	**Q&A, Discussion** • **Moderator: David R. Van Houte PhD**, Senior Manager - QC Virology, *Regeneron Pharmaceuticals*
17:20 – 17:20	**End of Conference Day 1 & Networking Event**	

Tuesday, 23 June

CEST Daylight Time (UTC +2:00)

09:00 – 09:05	**Welcome to Day 2** **Co-Chair: Chakameh Azimpour PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma* **Co-Chair: Remo Leisi PhD** Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety *CSL*	
09:05 – 10:30	**Session 4: Viral Safety in Process and Study Design** Virus clearance continues to play a key role in effectively controlling the residual risk in biological products and in ensuring that viruses that might be missed by sourcing and testing are effectively eliminated by the manufacturing process. The ICH Q5A R2 guideline allows for the use of platform approaches and prior knowledge, but implementation of these approaches can at times be challenging, and the extent to which prior knowledge can be applied needs to be justified. The application of AI or data-driven approaches to justify a reduced burden of virus clearance studies will be explored in this session, along with an update of one of the key PDA Technical Reports for the preparation of virus spikes used in virus clearance studies, Technical Report 47. **Moderator: Andy Bailey PhD**, CSO, *ViruSure GmbH*	
	09:05 – 09:25	**A Tale of Two Models: A Comparison of Mechanistic vs. Data-Driven Modeling Approaches for Viral Clearance** • **Presenter: Christina Caporale** , Engineer, *Cytiva*
	09:25 – 09:45	**Towards a Streamlined Viral Clearance Strategy for rAAV Processes** • **Presenter: Hannah Seo PhD**, Principal Scientist, *Bristol Myers Squibb*
	09:45 – 10:00	**Updates on Technical Report No. 47: Preparation of Virus Spikes Used for Virus Clearance Studies**
	10:00 – 10:30	**Q&A, Discussion**
10:30 – 11:00	**Networking Coffee Break, Poster Session & Exhibition**	
	Session 5: Other Concepts for Viral Safety Economic realities demand that the research-intensive pharmaceutical industry continually look for more efficient ways to produce biological medicinal products. In this context, multi-modal facilities promise to operate at greatly reduced costs yet raise questions about adequate biosafety and cross-contamination risk management. Also, alternative expression systems may offer advantages such as lower cost of goods or different product quality, yet do not come with decades of experience about how to successfully manage virus safety margins. **Moderator: Thomas R. Kreil PhD**, Vice President, Global Pathogen Safety, *Takeda*	
		Are Multi-Modal Facilities Possible? A Potential Roadmap

11:00 – 12:20	11:00 – 11:25	• **Presenter: Dana Schreffler MSc**, Sr. Mgr QC Viral Safety, *Regeneron Pharmaceuticals*
	11:25 – 11:45	**Engineering Safety in Novel Protein Expression: Lessons From the Use of L. Tarentolae to Express Glycoengineered Proteins** • **Presenter: Dominique Nicolas Sirena PhD**, Site Head & Chief Manufacturing Officer, *GlycoEra AG*
	11:45 – 12:20	**Q&A, Discussion**
12:20 – 13:20	**Networking Lunch Break, Poster Session & Exhibition**	
13:20 – 14:25	**Closing Session: Emerging Pathogens** The constant evolution of viruses leads to the ongoing emergence of new threats with potential impact on public health as well as concerns for the safety of biological therapies. Therefore, a proactive surveillance and assessment of viral outbreaks is an important element to ensure continued product safety. This session will include different perspectives to share current examples of recognized emerging viruses, approaches to systematically identify threats, as well as lessons learned from the SARS-CoV-2 pandemic and its impact on the biotech industry. **Moderator: Remo Leisi PhD**, Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety, *CSL*	
	13:20 – 13:35	**Ongoing and rather widespread circulation of a human-pathogenic virus in the United States that has gone largely unnoticed** • **Presenter: Thomas R. Kreil PhD**, Vice President, Global Pathogen Safety, *Takeda*
	13:35 – 13:50	**Automated Surveillance System to Monitor and Assess the Impact of New and Emerging Human and Animal Diseases on the Pathogen Safety of Biological Products** • **Presenter: Denis Klochkov PhD**, Head Product Ownership and Strategy, Global Pathogen Safety , *CSL Behring AG*
	13:50 – 14:05	**Industry Lessons from the SARS-CoV-2 Pandemic: Cross-Industry Insights from the CAACB Survey** • **Presenter: Chakameh Azimpour PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma*
	14:05 – 14:25	**Q&A, Discussion** • **Moderator: Remo Leisi PhD**, Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety, *CSL*
14:25 – 14:55	**Networking Coffee Break, Poster Session & Exhibition**	
14:55 – 15:00	**Passport Raffle Announcement** **Moderator: Melanie Decker** , , *Parenteral Drug Association*	
15:00 – 16:30	**Interactive Session**	
16:30 – 16:35	**Best Poster Presentation**	
16:35 – 16:45	**Co-Chairs Conference Summary** **Co-Chair: Chakameh Azimpour PhD**, Director - Virology and Microbiological Sciences, *EMD MilliporeSigma* **Co-Chair: Remo Leisi PhD** Head of Breakthrough Technologies & Technical Innovation, Global Pathogen Safety *CSL*	
16:45 – 16:50	**Closing Remarks & Farewell** **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*	

16:50 – 16:50	**End of Conference**