



2024 PDA Virus Conference
Amsterdam, The Netherlands
Viral Safety Reloaded - the Finalized ICH Q5A (R2)
26-27 June 2024

Agenda

Wednesday, 26 June 2024

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| 9:00 | Welcome and Introduction | Falk Klar, <i>PDA Europe</i> |
| | Welcome from the Co-Chairs | Andy Bailey, <i>VirusSure</i> Sean O'Donnell, <i>Eli Lilly and Company</i> |
| Opening Plenary | | Moderator: Andy Bailey, <i>VirusSure</i> |
| | Keynote: A Patient Perspective on Hemophilia | <i>Invited Speaker</i> |
| | Updates on ICH Q5A (R2) | <i>Paul Ehrlich Institut</i> |
| | Q&A, Discussion | |
| 10:45 | Coffee Break, Poster Session & Exhibition | |
| Session 1: Viral Safety of Advanced Therapies | | Moderator: Alison Armstrong, <i>Merck KGaA</i> |
| | Viral Safety Strategy for Adeno-Associated Virus Gene Therapy Products | <i>Alexion</i> |
| | The Design, Development, and Validation of Platform Methodology for Replication Competent Adeno Associated Virus | <i>Charles River</i> |
| | Virus Safety of Xenotransplantation | <i>Institute of Virology, Freie Universität Berlin</i> |
| | Q&A, Discussion | |
| 12:35 | Lunch Break, Poster Session & Exhibition | |



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| 13:15 | LIVE Guided Poster Walk Engage with our Poster Presenters in our Exhibition Hall | Moderator: Sebastian Teitz, <i>Consultancy</i> |
| | Interactive Questionnaire Session | Moderator: David Cetlin, <i>Cygnus</i> |
| Session 2: Virus Testing | | Moderator: Thomas R. Kreil, <i>Takeda</i> |
| | Next Generation Sequencing Implementation Strategies for Adventitious Virus Detection in Viral Vaccines and Biologics | <i>Johnson and Johnson</i> |
| | Approaches for Accelerated Adventitious Virus Testing and Strategies for Rapid Differentiation of Replicating Viral Infections from Inert Viral Sequences in Viral Vector Vaccines and Raw Materials | <i>IDT Biologika</i> |
| | Transcriptomic Next Generation Sequencing 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 | <i>PathoQuest</i> |
| | Q&A, Discussion | |
| 15:25 | Coffee Break, Poster Session & Exhibition | |
| Session 3: Novel Approaches and Digitization | | Moderator: Arifa Khan, <i>U.S. FDA</i> |
| | A Deep-Learning Classifier of Adventitious Agents | <i>MilliporeSigma</i> |
| | Automation of Virus Detection Assays Used in Virus Clearance Studies: From Liquid Handling to the Use of Machine-learning and Artificial Intelligence in Analyzing Cytopathic Effects | <i>CSL Behring</i> |
| | Adventitious Agent Testing for Minute Virus of Mice: How Much Do We Really Know? | <i>Takeda</i> |
| | Q&A, Discussion | |
| 17:25 | End of Conference Day 1 & Networking Event | |



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| 9:00 | Welcome to Day 2 | Andy Bailey, <i>VirusSure</i> Sean O'Donnell, <i>Eli Lilly and Company</i> |
| Session 4: Virus Inactivation and Virus Removal | | Moderator: Remo Leisi, <i>CSL Behring</i> Co-Moderator: Tomoko Hongo-Hirasaki, <i>Asahi Kasei</i> |
| | Inactivation of Hepatitis E Virus by Dry-Heat Treatment | <i>Octapharma Biopharmaceuticals</i> |
| | Viral Clearance Validation of Continuous Virus Filtration: Adapting Alternate Approaches to a New Manufacturing Paradigm | <i>Asahi Kasei</i> |
| | Virus Safety of Medical Devices Utilizing Animal Materials | <i>TÜV SÜD</i> |
| | Q&A, Discussion | |
| 10:15 | Coffee Break, Poster Session & Exhibition | |
| Session 5: Next Generation Sequencing | | Moderator: Simone Olgiati, <i>Merck KGaA</i> |
| | Evaluation of Next Generation Sequencing Performance for in vitro Detection of Viruses in Biological Products | <i>National Institute of Health Sciences</i> |
| | Head-to-Head Comparison of NGS with Vivo Animal Assays and In Vitro Cell Culture Assays for Adventitious Virus Detection | <i>U.S. FDA</i> |
| | Advanced Virus Detection Interest Group Spiking Study 3 - Sensitivity of High-Throughput Sequencing (HTS) Transcriptomics Analysis for Detection of Adventitious Viruses in a Cell Substrate Background | <i>GSK</i> |
| | Q&A, Discussion | |



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| 12:00 | Lunch Break, Poster Session & Exhibition | |
| | Interactive Questionnaire Session | Moderator: Sean O'Donnell, <i>Eli Lilly and Company</i> |
| Session 6: Sustainability | | Moderator: Sebastian Teitz, <i>Consultancy</i> |
| | The Development of a Sustainable Alternative Detergent to Triton X-100 | <i>Amgen</i> |
| | Eco-Friendly Detergent Inactivation and Clearance for a Hybrid-Continuous Process for Biologics Manufacturing | <i>Just-Evotec Biologics</i> |
| | Q&A, Discussion | |
| 14:15 | Coffee Break, Poster Session & Exhibition | |
| 14:45 | Passport Raffle via PDA Europe | |
| Closing Plenary | | Moderator: Sean O'Donnell, <i>Eli Lilly and Company</i> |
| | Center for Drug Evaluation and Research Updates on Viral Safety | <i>U.S. FDA</i> |
| | Title to be Advised | <i>Invited Speaker</i> |
| | Closing Panel Discussion Join our Discussion with Experts from the Academies, Industry, and Regulatory <ul style="list-style-type: none"> • <i>US. FDA</i> • <i>Paul Ehrlich Institut</i> • <i>Freie Universität Berlin</i> • <i>Takeda</i> | |
| | Co-Chairs Conference Summary | Andy Bailey, <i>VirusSure</i> Sean O'Donnell, <i>Eli Lilly and Company</i> |



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| | Closing Remarks & Farewell | Falk Klar, <i>PDA Europe</i> |
| 16:40 | End of Conference | |