2023 PDA Virus Conference
Virus Safety in the Era of ICH Q5A (R2)
Madrid, Spain
20-21 June 2023

Agenda

Tuesday, 20 June 2023

9:00	Welcome and Introduction	Falk Klar, *PDA*
9:05	Welcome from the Co-Chairs	Alison Armstrong, *Merck KGaA* Andy Bailey, *ViruSure*
Opening Plenary: International Regulatory Updates		**Moderator:** Alison Armstrong, *Merck KGaA*
Our first plenary session will establish the conference topic with presentations from international regulatory speakers selected from the EU, the US, and Asia. The speakers will touch on key points from the draft revision of ICH Q5A and will provide the most up-to-date understanding of viral risk mitigation as presented in this guidance. This draft regulatory document provides an up-to-date view of viral safety with increased scope to include well-established biological products and also new modalities such as viral vector products. The ability to use novel molecular-based technologies to address virus detection and the impact of a more flexible approach including platform validation and continuous viral inactivation for viral clearance will be discussed.		
	Update on Revision of Guideline ICH Q5A	Johannes Blümel, *Paul-Ehrlich-Institut*
	Technical Requirements for Platform Validation of Virus Clearance in Clinical Trial Applications and Strategies for Virus Safety Re-Evaluation of Process Changes	Wenbo Sai, *Center for Drug Evaluation* *-remote presentation-*
	Continuous Viral Inactivation or Lifecycle Management for Viral Safety: A Case Study	Sarah Johnson, *U.S. FDA*
	Q&A, Discussion	
11:15	**Coffee Break, Poster Session & Exhibition**	

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Session 1: Viral Clearance		**Moderator:** Tomoko Hongo-Hirasaki, *Asahi Kasei and* Sebastian Teitz, *Biopharma Excellence*
Within the basic concept of ICH Q5A which is commonly referred to as the "Virus Safety Tripod of Biopharmaceuticals", the pillar of virus clearance typically contributes the largest proportion in risk reduction to the biopharmaceutical product. This session will explore new approaches toward the measurement and detection of virus particles in the context of virus clearance studies and dive into the implementation and validation of virus filters into continuous processes.		
	Constant Flow Rate Viral Clearance Study of Planova™ BioEX Virus Removal Filter and Implementation into an End-to-End Continuous Process for mAb Purification	Hironobu Shirataki, *Asahi Kasei*
	Utilizing Retrovirus-like Particles (RVLP) to Evaluate Viral Clearance for Multiple Modes of Separation	David Cetlin, *Cygnus Technologies*
	Improvements of Integrated Cell Culture-RT-qPCR to Facilitate Rapid Detection of Non-Cytopathic Viruses	Remo Leisi, *CSL Behring*
	Q&A, Discussion	
13:15	**Lunch Break, Poster Session & Exhibition**	
14:00	**LIVE GUIDED POSTER WALK Engage with our Poster Presenters in our Exhibition Hall**	
Session 2: Round Table Discussions		**Moderators:** Arifa Khan, *U.S. FDA,* Johannes Blümel, *Paul-Ehrlich-Institut*
With the recently published draft revision of Guideline ICH Q5A, four main topics with a major impact on the viral safety strategy have been identified. The revision opens the possibility to use prior knowledge for validation of viral clearance. The scope of Guideline ICH Q5A will be extended towards new product types such as certain viral vectors and testing for residual helper viruses used at vector production. Last but not least, the revised draft guideline acknowledges the recent advances in using next generation sequencing for virus detection and the possibility of revising the adventitious agents testing strategy. Participants are invited to join specific subgroups to discuss their questions in an open scientific environment. Outcomes will be presented by the moderators to all participants.		

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14:30	Introduction to Round Table Discussions			
	Moderator: Sebastian Teitz, *Biopharma Excellence*	**Moderator:** Johannes Blümel, *Paul-Ehrlich-Institut*	**Moderator:** Alison Armstrong, *Merck KGaA*	**Moderator:** Andy Bailey, *ViruSure*
	Working Group 1 Viral Clearance	**Working Group 2** Testing for Residual Helper Viruses	**Working Group 3** New Product Types /Gene Therapies and Vaccines	**Working Group 4** Adventitious Agent Testing
	Summary of Round Tables			**Moderators:** Arifa Khan, *U.S. FDA,* Johannes Blümel, *Paul-Ehrlich-Institut*
16:00	**Coffee Break, Poster Session & Exhibition**			
Session 3: Virus Detection				**Moderator:** Andy Bailey, *ViruSure*
The ICH Q5A R2 document promotes the wider application of Next Generation Sequencing (NGS) and PCR-based technologies for the detection of potential virus contamination. This session will explore how NGS can be effectively implemented in any adventitious agent testing program and how this technology compares with more traditional, infectivity-based, approaches. Demonstrating that NGS has the sensitivity for a broad range of potential contaminants is key and the presentations will present case studies addressing these key aspects.				
	A Head-to-Head Comparison of Next Generation Sequencing (NGS) with Conventional Assays for Adventitious Virus Detection			Arifa Khan, *U.S. FDA and* Shawn Polson*, Center for Bioinformatics and Computational Biology, University of Delaware, Newark,*
	Applying Next Generation Sequencing Technologies for Virus Safety Testing in a “Revision 2” World			Bradley Hasson and Afshin Sohrabi, *Merck KGaA*
	Q&A, Discussion			
17:50	**End of Conference Day 1 & Networking Event**			

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Wednesday, 21 June 2023		
9:00	**Welcome to Day 2**	Alison Armstrong, *Merck KGaA* Andy Bailey, *ViruSure*
Session 4: Next Generation Sequencing - Efforts in the Advanced Virus Detection Interest Group (AVDTIG)		**Moderator:** Arifa Khan, *U.S. FDA*
The AVDTIG is a multidisciplinary international effort with a focus on developing standards and conducting collaborative studies for performance evaluation and 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. Details of two spiking studies, which are completed/near completed, will be presented. The session will close with audience Q&A and discussion.		
	General Updates from the Interest Group, Subgroups, and Collaborative Studies	Arifa Khan, *U.S. FDA,* Siemon Ng, *Notch Therapeutics* *-remote presentation-*
	Status of Spiking Studies #2A (Minute Virus of Mice in Cellular Background) and #4 (Evaluation of Long-Read Sequencing)	Simone Olgiati, *Merck*
	Study #3: Cell Transcriptomics Study for Evaluating Adventitious Virus Detection in Cell Substrates	Noemie Deneyer, *GSK*
	Study #2B: Five Model Virus Spiking Study to Evaluate Adventitious Virus Detection in a Viral Seed or Vector Preparation	Christophe Lambert, *GSK*
	Q&A, Discussion	
10:20	**Coffee Break, Poster Session & Exhibition**	
Session 5: Manufacturing-Related Aspects		**Moderator:** Sean O'Donnell, *Eli Lilly and Company*
Biopharmaceutical manufacturers are continually looking for ways to rapidly detect and prevent adventitious virus contamination and remove endogenous viruses in the manufacturing processes. High-Temperature Short Time (HTST) is a common method that is employed by manufacturers to inactivate any potential		

contamination in cell culture media and feeds, but implementation can be costly and take a lot of development time. In this session, the use of upstream virus filters to remove viral contamination from media and feeds will be discussed. Also, the use of PCR to detect endogenous viral loads in unprocessed bulk harvests and Xenotropic murine leukemia virus (X-MuLV) removal during the Protein A column chromatography unit operation will also be discussed.		
	Nucleic Acid Based Assays for Upstream Mitigation and Bulk Harvest Testing	Chakameh Azimpour, *Amgen* *-remote presentation-*
	Characterization of Upstream Viral Filters for Virus Retention of Media and Feeds	Benjamin Walker, *Eli Lilly and Company*
	Q&A, Discussion	
12:10	**Lunch Break, Poster Session & Exhibition**	
Closing Plenary: Current Strategies and Challenges in the Future		**Moderator:** Andy Bailey, *ViruSure*
This session will start with an interactive question and answer poll of the conference participants using Mentimeter on various aspects of virus safety of relevance to the conference. The ICH Q5A R2 guideline presents several new aspects and challenges for meeting the regulatory requirements around virus safety. Much of what the industry has learned in more than 30 years of performing virus clearance studies is reflected in the ICH Q5A R2 document and the first presentation of this session will explore how these changes will impact how we perform such studies going forward. The second presentation will address how the new guidance impacts the whole package of adventitious agent testing for a well-characterized Chinese Hamster Ovary (CHO)-derived product. At the end of the session, participants are invited to join in a panel discussion with distinguished virus safety experts from both industries as well as regulatory agencies for a lively discussion around the revised requirements for virus safety testing.		
	Interactive Questionnaire Session	
	Viral Clearance – Where Do We Go?	Horst Ruppach*, Charles River*
13:55	**Coffee Break, Poster Session & Exhibition**	
14:25	**Passport Raffle**	

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	Virus Safety Strategies for Chinese Hamster Ovary (CHO) Cell-Derived Products Using ICH Q5A R2 Guidance	John Fisher, *Genentech/Roche*
	Closing Panel Discussion Join our Discussion with Experts from the Industry and Regulatory • Alison Armstrong, *Merck KGaA* • Johannes Blümel, *Paul-Ehrlich-Institut* • Sarah Johnson, *U.S. FDA* • Arifa Khan, *U.S. FDA* • John Fisher, *Genentech/Roche* • Horst Ruppach, *Charles River*	**Moderator:** Andy Bailey, *ViruSure*
	Co-Chairs Conference Summary	Alison Armstrong, *Merck KGaA* Andy Bailey, *ViruSure*
	Closing Remarks & Farewell	Falk Klar, *PDA*
16:00	**End of Conference**	