



2023 PDA Viral Safety for ATMPs Workshop

Understanding the Challenges and Risk Mitigation Strategies

Madrid, Spain

19 June 2023

Agenda		
Monday, 19 June 2023		
10:00	Welcome and Introduction	Falk Klar, <i>PDA</i> Sean Michael O'Donnell, <i>Eli Lilly and Company</i>
Topic: Viral Safety of Raw Materials for Cell Therapy		Moderator: Sean Michael O'Donnell, <i>Eli Lilly and Company</i> Co-Moderator: Sebastian Teitz, <i>Biopharma Excellence</i>
10:05	Viral Safety of Cell Therapy	Johannes Blümel, <i>Paul-Ehrlich-Institut</i>
10:25	Evolving Towards Safer Ancillary Materials: Viral Clean-up of Human Platelet Lysate	Roman Goetzke, <i>PL BioScience</i>
10:50	Nanofiltration of Growth Media Supplemented with Human Platelet Lysates for Pathogen-Safe Xeno-Free Expansion of Mesenchymal Stromal Cells	Thierry Burnouf, <i>Taipei Medical University (TMU)</i> <i>-remote presentation-</i>
11:15	Coffee Break	
11:45	Open Group Discussion The following topics will be evaluated with inputs from the audience. <ul style="list-style-type: none"> • Raw Material Qualification • Testing Methods • Inactivation Procedures 	Moderator: Andy Bailey, <i>Virusure</i> Co-Moderator: Arifa Khan, <i>U.S. FDA</i>



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	Interactive Questionnaire Session	
12:45	Lunch Break	
	Topic: Downstream Virus Removal for Viral Vector Products	Moderator: Alison Armstrong, Merck KGaA Co-Moderator: Johannes Blümel, Paul-Ehrlich-Institut
13:45	Virus Safety of Adeno-associated Virus (AAV) Vector Products (Virus Clearance and Testing for Helper Viruses)	Anurag Sharma, US FDA -remote presentation-
14:10	A Platform Approach to the Development and Validation Replication of Competent Assays for Viral Vector Products	Amy Bennett, Charles River
14:35	Standardizing Viral Vectors: Outcomes from a Workshop on Metrology for Viral Systems as Molecular Tools	Jonathan Campbell, LGC Group
15:00	Coffee Break	
15:30	Open Group Discussion Topics from the audience and the results from the previous interactive questionnaire session will be discussed.	Moderator: Andy Bailey, ViruSure Co-Moderator: Arifa Khan, U.S. FDA
16:30	Summary of the Workshop and Take-Home Messages	Sean Michael O'Donnell Eli Lilly and Company
16:55	Farewell	Falk Klar, PDA



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17:00	End of Workshop	
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The program is subject to changes.