



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> |



2023 PDA Viral Safety for ATMPs Workshop

Understanding the Challenges and Risk Mitigation Strategies

Madrid, Spain

19 June 2023

| | | |
|--------------|--|---|
| | 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 | Bolstering Virus Contamination Prevention: A Case Study of Cell Culture Medium Quality | Manjula Aysola, Merck |
| 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 |
| 16:30 | Summary of the Workshop and Take-Home Messages | Sean Michael O'Donnell Eli Lilly and Company |
| 16:55 | Farewell | Falk Klar, PDA |
| 17:00 | End of Workshop | |

The program is subject to changes.