



VIRUSURE

# 4<sup>th</sup> Virus Safety Workshop

AsahiKASEI  
BIOPROCESS

## New Frontiers in Biosafety Testing

- 08:30 Registration
- 08:50 Welcome Introduction  
*Andy Bailey, ViruSure GmbH*

### Evolving Regulatory Landscape

- 09:00 Draft Pharmacopoeia Chapter 2.6.41 on High-Throughput Sequencing for the detection of viral extraneous agents  
*Johannes Blümel, Paul-Ehrlich-Institute (PEI)*
- 09:30 Prior knowledge - an assessor's view  
*Martin Spruth, Agentur für Gesundheit und Ernährungssicherheit (AGES)*
- 10:00 Practical considerations in application of ICH Q5A (R2) to ensure virus safety of biological products  
*Andy Bailey, ViruSure GmbH*
- 10:30 Break

### The Power of NGS: Case Studies

- 11:00 The application of Oxford Nanopore long-read sequencing technology for biosafety testing of biological products  
*Hans-Peter Fasching, ViruSure GmbH*
- 11:30 TBD
- 12:00 Adventitious Virus Testing of Oncolytic Virus Therapeutics  
*Michael Ruffing, Boehringer Ingelheim Pharma GmbH & Co KG*
- 12:30 Lunch

### What can we learn from Plasma industries?

- 13:30 Virus Safety Concepts: What Can We Learn from the Plasma Industry Takeda  
*Thomas R. Kreil - Takeda*
- 14:00 Virus and prion clearance for products from human plasma – case reports  
*Marcel Asper, Biotest AG*
- 14:30 Leveraging Planova Filtration Insights: Lessons from the Plasma Industry for ATMPs Manufacturing  
*Roya Dayani, Asahi Kasei Bioprocess Europe (AKBE)*
- 15:00 Break

### Testing strategies for ATMPs

- 15:30 *Alejandra Leivas, Gradocell*
- 16:00 Precision in Every Drop: High-Accuracy Negative Staining TEM for AAV Characterization – A Validated Comparison with Orthogonal Methods  
*Ashley Stephen Layland, neotem Bioanalytics-IIT GmbH*
- 16:30 TBD
- 18:00 Lab Tour & Drinks

### Date

3<sup>rd</sup> April, 2025

### Location

TechGate Technology Building  
Donau-City-Strasse 1  
1220 Vienna, Austria

### Cost

250 EUR

### Contact

[virussafety@virusure.com](mailto:virussafety@virusure.com)

### Registration

[VirusSure 4th Virus Safety Workshop](#)