

Chairs, Speakers, and Presentations

*The program is subject to change.

*Chairs and Speakers in order of program.

June 20,2025

Day 1: 13th November (Thursday), 2025

Fundamentals and Regulatory (Chair: Thomas Kreil Ph.D., Associate Professor of Virology, Vice President, Global Pathogen Safety, Takeda)	
8:45 - 9:15	New Chapter in the European Pharmacopeia on High-Throughput Sequencing for the Detection of Viral Extraneous Agents Johannes Bluemel, Ph.D., Head of Viral Safety Section, Infectiology, Paul-Ehrlich-Institute
9:15 - 9:45	Enhancing Viral Safety: Prior Knowledge and Platform Virus Clearance Strategies in the Era of ICHQ5A (R2) Andy Bailey, Ph.D., CEO, ViruSure GmbH
9:45 - 10:15	Implications of the ICHQ5A (R2) on Viral Clearance Studies Scopes Anja Tessarz, Ph.D., Associate Director R&D, SME Viral Clearance, Charles River Laboratories Germany GmbH

Coffee Break & Poster Session

Nanofiltration of Challenging Plasma Derived Proteins (Chair: Elisa Moretti, PhD., Senior Director Global Pathogen Safety/Global Manufacturing Science & Development (GMSD), Kedrion Biopharma)		
10:45 - 11:15	Robustness Study of Planova S20N (TBC)	
11:15 - 11:45	Changes in Nanofilters: Case Studies for Switching to State-of-the-Art Nanofilters in Established and Developing Manufacturing Processes Martyn Paddick, Ph.D., Director Global Process Development & Industrialization, Kedrion Biopharma	
11:45 - 12:15	Mechanistic Insights into Virus Filtration Process by Direct Visualization of Retention Profiles Remo Leisi, Ph.D., Head of Breakthrough Technologies & Technical Innovation, CSL	

Lunch Break

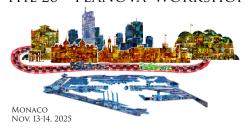
Rapid Nanofiltration Enabling Highly Efficient Processing (Chair: Uwe Gottschalk, PhD., Operating Partner, Keensight Capital former Lonza CSO)	
13:30 - 14:00	Evaluation of Planova FG1 Virus Filter: Enhancing Efficiency and Addressing Filterability Challenges in a Diverse Therapeutic Antibody Pipeline Ludivine Profit, Scientist, Purification Process Development, Sanofi
14:00 - 14:30	Evaluation of Planova S20N on a Challenging mAb Solution Prone to Aggregation (TBC)
14:30 - 15:00	Evaluation of Planova FG1 (TBC)

Poster Session	
15:00 - 16:00	Study of Superior Microfiltration Membrane Structure for Perfusion Cell Culture: Influence of Cell Density and Shear at Membrane Surface on Filtration Performance Shun Matsuda, Scientist, Research and Technology Development Div., Asahi Kasei Life Science Co., Ltd.
	Non-Pressurized Membrane Concentration for Pharmaceutical Manufacturing: Forward Osmosis and Membrane Distillation Junji Sakuda, Ph.D., Manager, Corporate Research & Development, Asahi Kasei Corporation
	The Features of Membrane Structure and Production Method of BioOptimal UMP and MFSL Filters Yuki Miki, Chief Researcher, Microza Research & Development Department., Asahi Kasei Corporation





THE 26TH PLANOVA" WORKSHOP



Chairs, Speakers, and Presentations

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June 20,2025

Day 1: 13th November (Thursday), 2025

Poster Session	
15:00 - 16:00	Hybrid PCR-Based Mycoplasma Detection for Product-Specific Suitability and USP<63> Comparability for High Cell Density Products Lori Daane, Ph.D., Chief Scientific Officer, Bionique Testing Laboratories LLC
	A Comparison of Planova FG1 Virus Filter Performance and Product Quality on Various Modalities of Biologics Minni Aswath, Vice President, Process Development, Bionova Scientific LLC
	GMP Implementation of Oxford Nanopore's Long-Read Sequencing Technology for the Detection of Adventitious Viruses in Biopharmaceutical Products Hans-Peter Fasching, Deputy Head of Molecular Biology Department, ViruSure GmbH

Social Activity

Day 2: 14th November (Friday), 2025

Cell Culture Clarification with Tangential Flow Microfiltration (Chair: Ashley Baltes, Scientific Director, Just-Evotec Biologics, Inc.)		
8:30 - 9:00	Cell Culture Clarification with Tangential Flow Microfiltration in a Perfusion Production (TBC)	
9:00 - 9:30	Intensification Strategies for Adeno Associated Virus Production Processes Thomas Villiger, Ph.D., Professor of Bioprocess Technology, University of Applied Sciences and Arts Northwestern Switzerland FHNW	
9:30 - 10:00	Optimizing TFF Hollow Fiber Filtration for Scalable Perfusion Bioprocessing Patrick Romann, Ph.D., Bioprocess Innovation Manager, R&D, Levitronix	

Coffee Break & Poster Session

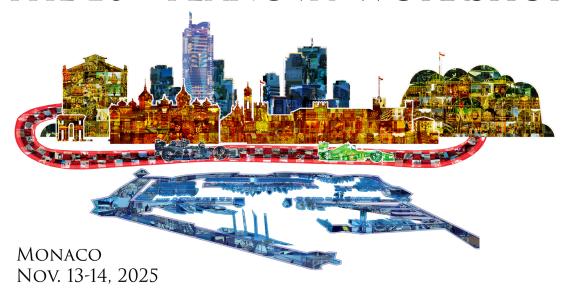
New Trends and Applications (Chair: Alex Harley, SME – Viral Clearance, Downstream Process Development, FUJIFILM Biotechnologies)		
10:30 - 11:00	Media Nanofiltration for Advanced Therapy Medicinal Products (ATMP) (TBC)	
11:00 - 11:30	Exploring the Approach for rAAV Downstream Early-Stage Viral Clearance Study Yu-Tsan (Richard) Liu, Senior Scientist, Gene Therapy Process Sciences Downstream, UCB Pharma SA	
11:30 - 12:00	Evaluation of Viral Filter Performance in an End-to-End Continuous Process Jodi Chen, Scientist, Purification, PD, Just-Evotec Biologics	

Lunch





THE 26th Planova™ Workshop



······ Program at a Glance ······



The agenda will be finalized a few weeks prior to the event.

Join us at the Workshop in Monaco!

Register <u>here</u> to attend The 26TH Planova[™] Workshop, Monaco

Registration fee: 200 EUR per person

https://kuonicongress.eventsair.com/asahikasei/

We have negotiated a special rate of 210Euro/night (incl. breakfast and taxes) for your stay during Planova Workshop. To benefit this rate, please register yourself first and receive the special rate link!

Venue: Le Méridien Beach Plaza

22 Av. Princesse Grâce, 98000 Monaco
For inquiries, please reach out to us at <u>ASAHIWS2025@akbio.eu</u>



