



THE 25TH PLANOVA™ WORKSHOP

CHICAGO | OCT. 10-11 2024

Chairs, Speakers, and Presentations

September 24, 2024

Day 1: Thursday, October 10, 2024

Viral Safety and ICH-Q5A(R2)

(Chair: Thomas R. Kreil, Ph.D., Vice President, Global Pathogen Safety, Takeda Manufacturing Austria)

8:45 - 9:15

Update on ICHQ5A and European Regulations

Johannes Bluemel, Ph.D., Head of Virus Safety Section, Virology, Paul-Ehrlich-Institut (PEI)

9:15 - 9:45

ICH Q5A R2: Practical considerations in application of the new guideline to ensure virus safety

Andy Bailey, Ph.D., CEO, Biosafety Testing Services, ViruSure

9:45 - 10:15

ICH Q5A(R2): Contributions and Prospects for Scientific Knowledge on Virus Filtration

Tomoko Hongo-Hirasaki, Ph.D., Lead Expert, Scientific Affairs, Bioprocess Division, Asahi Kasei Medical

Virus Filtration for Robust Processes

(Chair: Sean O'Donnell, Ph.D., Executive Director, Virology and Purification Development, Eli Lilly)

10:35 - 11:05

Viral Clearance and Filtration Evaluation of Monoclonal Antibodies using Planova BioEX and S20N Filters

Melanie Bell, Research Associate III, Purification, Process Development, Pfizer

11:05 - 11:35

Exploring the Impact of pH, Conductivity, and Transmembrane Pressure on MVM Removal Using Two Monoclonal Antibody Processes and Three Virus Filter Types

Ashton Dacon, Process Development Engineer I, Preclinical Manufacturing and Process Development, Regeneron Pharmaceuticals

11:35 - 12:05

Implementation of nanofiltration step at early bioprocess development stage. Filter selection

Natalia Ugulava, Ph.D., Senior Principal Scientist, Early BioProcess Development (EBPD), Pfizer

12:05 - 12:35

Visualizing the Impact of Immune Complex Formation on Virus Retention in Planova Filter Membranes

Emily Alexander, Ph.D., Head GPS Material Safety, R&D, CSL

Cell Culture Clarification Using Microfilters

(Chair: Mark Brower, Ph.D., Senior Director, Process Research & Development, Merck & Co., Inc.)

1:30 - 2:00

Effect of inner diameter, filter length, and pore size on hollow fiber filter fouling during perfusion cell culture

Andrea Squeri, Scientist, Bioprocess Technologies and Engineering, Biopharmaceutical Development, AstraZeneca

2:00 - 2:30

Development of TFF by BioOptimal MF-SL for bioreactor clarification and recovery of AAV capsids

Ranil Wickramasinghe, Ph.D., Distinguished Professor, Chemical Engineering, University of Arkansas

2:30 - 3:00

Same CHO, different product: leveraging mAb perfusion experience to establish intensified vaccine upstream processes

Mark Brower, Ph.D., Senior Director, Process Research & Development, Merck & Co., Inc.

New Product Unveiling



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3:10 - 4:30

Poster Session

Successful Viral Filtration of Drug Substances with Self Associating Domains Using the Planova S20N

Ivan Loukinov, Senior Associate Scientist, Downstream Process Development, NIH/NIAID/VRC/VPP

An Evaluation of Planova 20N versus S20N for Implementation in an IgG4 Manufacturing Process

Yong Yow, Ph.D., Senior Scientist, Downstream Process Development, KBI Biopharma

Enhancing Virus Filtration Efficiency by Optimizing Load Conditions and Adding Specific Prefilters

Dylan Gechtman, Associate Scientist, Downstream Process Development, Bionova Scientific

NGS - Identification of the Unknown - A case study

Ralf Klein, Ph.D., Director of Business Development, Business Development and Marketing, ViruSure

Posters from Asahi Kasei Bioprocess America

Day 2: Friday, October 11, 2024

New Technologies & New Applications

(Chair: Susan M. Liu, Ph.D., Director, Protein Therapeutics API Development, Johnson & Johnson)

9:00 - 9:30

Virus safety concepts for new medical biotechnology modalities

Thomas R. Kreil, Ph.D., Vice President, Global Pathogen Safety, Takeda Manufacturing Austria

9:30 - 10:00

Viral Clearance Evaluation for AAV Therapeutics

Delaney Dowdell, Downstream Engineer, Downstream Process Development, Viral Vector Product Development, Alexion AstraZeneca Rare Disease

10:00 - 10:30

Comparison of Viral Filter Performance in an End-to-End Continuous Process

Jodi Chien, Senior Associate Scientist, Process & Product Design, Just-Evotec Biologics, Inc.

11:00 - 11:30

A New High Flux Planova Filter – The Future of Virus Filtration Has Arrived

Daniel Strauss, Ph.D., Director and Lead Expert, Research & Development, Asahi Kasei Bioprocess America

11:30 - 12:00

Evaluation of a new generation viral filter

Sean O'Donnell, Ph.D., Executive Director, Virology and Purification Development, Eli Lilly