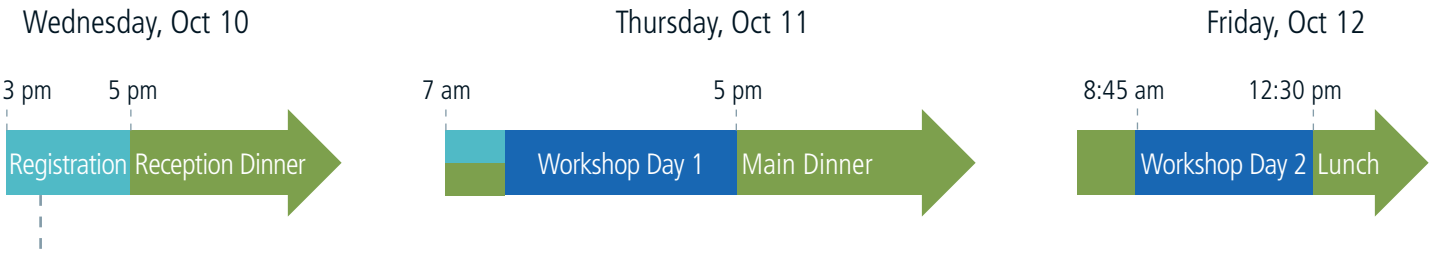
THE 21ST PLANOVA™ WORKSHOP

SAN FRANCISCO
OCTOBER 11 - 12, 2018

Program at a Glance



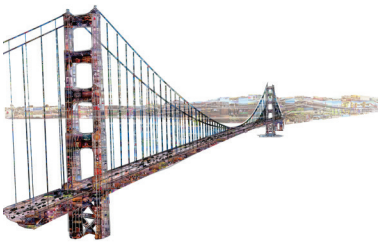
Complimentary bus departs the Charles River Laboratories Viral Clearance and Safety Summit at 3:30 pm

Join us at the Workshop in San Francisco!

Register to attend the Workshop
USD 250 per person
www.planovaworkshop2018.rsvpify.com

Reserve your stay at the Grand Hyatt Hotel Union Square (optional)
USD 329 + tax per night
Reservations can be made by contacting us at WS2018@ak-bio.com (include check in/check out dates).
We will confirm room availability, and all further arrangements will be handled by the hotel.

AsahiKASEI
BIOPROCESS



THE 21ST PLANOVA™ WORKSHOP

October 2, 2018

Dear Valued Customers,

Next week, we will host the 21st Planova™ Workshop in San Francisco where professionals in the fields of regulation, process development, pathogen safety, quality and manufacturing will gather from around the world to deepen their knowledge of the best practices in virus filtration.

The 21st Planova™ Workshop
Grand Hyatt Hotel Union Square
San Francisco, CA, USA
October 11 and 12, 2018
Reception Dinner on Wednesday, October 10

This year's theme is achieving successful virus filtration of challenging molecules. Our speakers are preparing presentations to share their experience in virus filtration of molecules, including ones with challenging molecule properties, process conditions or process development considerations. Chairs, speakers and presentation titles are shown on the next page.

We would love for you to join us in this year's Planova Workshop in San Francisco, one of the centers of biotechnology. This event will be the largest Planova workshop we have ever hosted in the US, as we have already received an astonishing number of registrations from the US, Europe and Asia! There is still room for you to attend. Make your plans to join us today!

For further information, please contact us:

Ms. Lena Liu
+1 847-834-0932

Ms. Yumiko Nishino
+1 847-834-0925

WS2018@ak-bio.com

We look forward to seeing you in San Francisco! More information is available on our Workshop website:
https://planova.ak-bio.com/planova-workshop/

Sincerely,

Hirotomi

Naokatsu Hirotomi
Executive Vice President and General Manager
Asahi Kasei Bioprocess America, Inc.

SPEAKERS AND PRESENTATIONS

Day 1: Thursday, October 11, 2018

CHAIR: Barry D. Gooch, Ph.D.
Associate Director, Pathogen Safety NC, BioScience Research Group, Grifols

Virus Filtration Fundamentals

8:45 am	**Update on European Regulations** Johannes Blümel, Ph.D., Head of Virus Safety Section, Department of Virology, Paul-Ehrlich-Institut
9:15 am	**A Review of Virus Filter Performance—Critical Process Parameters and Best Practice** Horst Ruppach, Ph.D., Director, Viral Clearance and Virology, Biologics Testing Solutions, Charles River Laboratories
9:45 am	**Overview of Challenges in Virus Filtration: Principles and Applications** Tomoko Hongo-Hirasaki, Ph.D., Senior Scientist of Evaluation and Analysis in Virus Filtration, Bioprocess Division, Asahi Kasei Medical
10:45 am	**Establishing a Virus Filter Design Space—Impact of Process Interruption on Parvovirus Retention** Ashlee Smith, Associate Scientist, BioTherapeutics Development - API; Discovery, Product Development & Supply, Janssen Research & Development
11:15 am	**Different Apparent Size of Parvoviruses Determined by Virus Filtration** Thomas Nowak, Ph.D., Senior Manager, Pathogen Safety, CSL Behring
11:45 am	**Direct Visualization of Behavior of Virus and Proteins in Planova™ Membrane Filters Using Advanced Microscope System with Confocal Optics** Takayuki Nishizaka, Ph.D., Professor, Department of Physics, Gakushuin University

CHAIR: Rachel Specht, Ph.D.
Technical Development Senior Scientist, Process Virology, Pharma Technical Development, Genentech, a member of Roche Group

Process Development

1:15 pm	**Case Study: Evaluation of the Effects of Process Pause and Pressure Variation on Planova™ 20N Virus Filter** Samuel Vollert, Process Development Scientist I, Downstream Process Development, Thermo Fisher Scientific
1:45 pm	**Perspective on Viral Filter Selection and Viral Clearance Assessment from a Biology-First Portfolio** Ben Tillotson, Ph.D., Senior Scientist, Drug Substance Technologies, Amgen
2:15 pm	**Nanofiltration: A BioEX Driven Platform Assessment** Doug MacDonald, Senior Scientist, BioProcess Development, Seattle Genetics
3:15 pm	**Clarification Impurities Impact Viral Filtration of a Therapeutic Antibody** Ryan Zolyomi, Senior Development Associate, Isolation & Purification, Biological Development, Bayer US
3:45 pm	**Strategy for Virus Filtration Challenges** Matt Luo, Ph.D., Executive Director Haikuan Liu, Ph.D., Associate Director, Downstream Process Development, Wuxi Biologics (Shanghai)

DAY 2: Friday, October 12, 2018

CHAIR: Ashley Hesslein, Ph.D.
Associate Director, Isolation & Purification, Biological Development, Pharmaceuticals, Bayer US

Robust Manufacturing & New Trends

8:45 am	**Meeting Planova™ and Selecting BioEX for Our Monoclonal Antibody (mAb) Manufacturing Process** Yumiko Masuda, Scientist, Biologics Technology Research Laboratories, Biologics Division, Daiichi Sankyo
9:15 am	**Of Future Biotechnology Options, and the Central Role of Nanofiltration** Andreas Wieser DI (FH), Senior Laboratory Associate, Global Pathogen Safety, Shire
9:45 am	**Use of a Non-Infectious Surrogate to Predict Minute Virus of Mice Removal During Nanofiltration** David Cetlin, Founder/C.E.O., MockV Solutions
10:45 am	**Evaluating the Impact on Viral Clearance of Multiple Unplanned Interruptions During Virus Removal Filtration** Kevin K. Okimura, Senior Manager, Outsourced Manufacturing, Portola Pharmaceuticals
11:05 am	**Virus Filtration in Continuous Processing** Bastian Budde, Ph.D., Senior Expert Process Development, Downstream, Process Development, Bayer AG
11:35 am	**Challenges of Implementing Virus Filtration into Continuous Manufacturing** Daniel Strauss, Ph.D., Principal Scientist, Science and Technology, Asahi Kasei Bioprocess America