

Viral Safety and Raw Materials

Part of
BioProcess
International
Europe

2-5 April 2019

Messe Wien Exhibition Congress Center, Vienna

DRIVE VIRUS DETECTION, VIRAL REMOVAL & REGULATORY KNOW-HOW

Leading Viral Safety Experts Share Unpublished Data



Bonnie Shum
Senior Engineer
Genentech



Laurent Mallet
Senior Director
Sanofi-Pasteur



Arifa Khan
Supervisory
Microbiologist
FDA



Albert Stühler
Deputy Head
Paul-Ehrlich-Institut

Online Registration Closes 27 March • Register Today

<https://lifesciences.knect365.com/viral-safety/>

ENSURE REGULATORY COMPLIANCE FROM RAW MATERIALS THROUGH TO THE SAFETY OF YOUR FINISHED PRODUCT



SCIENCE

Access innovative science from global viral safety and raw material experts who will present case studies and new data on:

- Raw Materials Variability, Sourcing and Supply Chain
- Process Intensification and Considerations for ATMPs
- Regulations, NGS, Risk Assessment & Facility Design



TECHNOLOGY

Stay at the forefront of viral safety innovation by viewing live product demonstrations from 120+ global CROs, CMOs and suppliers that cater to the global biologics industry.



NETWORKING

Discuss your current challenges with like-minded scientists, engineers and executives working across viral safety and raw material development. Plus, your registration also includes access to the main conference sessions and 900 attendees of the co-located BioProcess International Europe meeting.

Wednesday 3rd April 2019

- 7:30 *Registration & Coffee*
- 8:20 **Chairperson's Remarks**
Thomas R. Kreil, Senior Director Global Pathogen Safety, *Shire, Austria*
- 8:30 **Ask the Regulators – Regulatory Breakfast Briefing**
Albert Stühler, Deputy Head of Section, Viral Safety, *Paul-Ehrlich Institut, Germany*
Arifa Khan, Supervisory Microbiologist, *CBER, U.S. Food and Drug Administration, USA (pending final confirmation)*
- 10:00 **Spotlight Presentation**
A Representative from *Merck*
- 10:30 *Networking Refreshment Break*
- 11:30 **Continuous Virus Inactivation Process Using a Novel Packed-Bed Reactor**
Duarte Martins, PhD Student, Lab of Protein Technology and Downstream Processing, Dept of Biotechnology, *University of Natural Resources and Life Sciences, Vienna*
- 12:00 **Virus Inactivation by Laboratory and by Manufacturing Scale UV-C Irradiation in Products of Human Plasma**
Marcel Asper, Director Virus Laboratory, Pathogen Safety, *Biotest AG, Germany*
- 12:30 **Spotlight Presentation**
A Representative from *Pall LifeSciences*
- 13:00 *Networking Lunch in the Poster & Exhibit Hall*
- 13:30 **Live Labs**
- 14:15 **Environmental Restrictions and Use of Alternatives to Triton X-100 in Virus Inactivation**
Johanna Kindermann, Manager, Pathogen Safety, *Shire, Austria*
Jean-Baptiste Farcet, Senior Development Scientist, Process Development, *Shire, Austria*
- 14:45 **Effective Inactivation of a Wide Range of Viruses by Pasteurisation**
Wolfram Schäfer, Senior Manager, Virus Safety Development, *CSL Behring, Germany*
- 15:15 **Spotlight Presentation**
A Representative from *Sartorius*
- 15:45 *Networking Refreshment Break*
- 16:15 **Roche Diagnostics GmbH Case Study**
Marc Bieberbach, Senior Research Associate, *Roche Diagnostics GmbH, Germany*
- 16:45 **Upstream Viral Risk Mitigation Strategy for High Titer Biologics Manufacturing**
Dave Kolwyck, Director Manufacturing Science, Raw Materials, *Biogen Idec, USA*
- 17:15 *Plenary Changeover*
- 17:20 **CLOSING PLENARY: Next Generation Bioprocessing Strategies**
A Representative from *Sartorius*
- 17:50 **CLOSING PLENARY: Industry 4.0 in Aviation – Digitalization without beta versions**
Sven Taubert, Head of Corporate Foresight & Market Intelligence, *Lufthansa Technik AG, Germany*
- 18:20 *End of Day Two and Evening Party*

Thursday 4th April 2019

- 8:20 *Chairperson's Opening Remarks*
- 8:30 **Examining the Advances and Challenges in Vaccine Development and Manufacture**
Tony D'Amore, PhD, MBA, Vice President, Product Research and Development, *Sanofi Pasteur*
- 9:00 **KEYNOTE: Operating in a Disruptive Bioprocessing Landscape – Next Generation Bioprocessing Technologies, Facility Design and Products to Improve Process Productivity and Increase Capacity**
Brendan Hughes, Vice President, *MS&T, BMS, USA*
- 9:30 **Smart Biomanufacturing Facilities of the Future**
A Representative from *IDBS*
- 10:00 *Morning Coffee & Poster Tour 1*
- 10:45 **Next generation sequencing efforts at CBER**
Arifa Khan, Supervisory Microbiologist, *CBER, U.S. Food and Drug Administration, USA (pending final confirmation)*
- 11:15 **Testing Strategies for Adventitious Agents: Impact of NGS Introduction**
Laurent Mallet, Global Head, Analytical Sciences, *Sanofi Pasteur, France*
- 11:45 **Spotlight Presentation**
A Representative from *Charles River*
- 12:15 *Lunch In The Exhibition Hall and Live Labs*
- 13:30 **Rapid Methods for Adventitious Virus Detection and Sterility Assurance: How can we achieve broad adoption**
Cristina Barbirato, Senior Scientist, *Merck MSD, BPOG, Italy*
- 14:00 **Next-Generation Sequencing vs Traditional Methods: Considerations and Proof of Concept Data for the Development of a Next-Generation Sequencing Method for Adventitious Virus Detection**
Maria M. Bednar, Scientist I, *AT Virology, Biogen, USA*
- 14:30 **Viral Segregation Strategy for New Facility Designs**
Bonnie Schum, Senior Engineer, Global Biologics Manufacturing Sciences and Technology (MSAT), *Genentech, USA*
- 15:00 **Spotlight Presentation**
A Representative from *SGS*
- 15:30 *Afternoon Coffee and Poster Tour 2*
- 16:15 **Circulation of HEV in Europe – implications for blood / plasma product safety**
Maria Farcet, Manager, Pathogen Safety, *Shire, Vienna*
- 16:45 **Viral Clearance Testing in a Continuous Manufacturing Process**
Konstantin Zöller, Fellow, Scientific leader, Gene Therapy, Pilot Scale Manufacturing, Viral Safety, *Novartis, Switzerland*
- 17:15 *End of BioProcess International Europe*



8:00 *Registration*

Monitoring and Control Strategy for Batch and Continuous Bioprocesses

8:30 Chairperson's Opening Remarks

Margit Holzer, Scientific Director, **Ulysse Consult**, *Luxembourg*

8:35 • Definitions

- Regulatory background
- Overview of Bioprocess Controls for USP and DSP – What & Why & When to measure & control
- Important requirements on process monitoring & control loops – from sampling, measuring, visualization, software, equipment and feed-back or feed-forward controls
- Measuring points, frequency, data treatment and storage
- Control hierarchies
- Routine operation, cleaning, calibration, maintenance
- Main differences between batch and continuous bioprocess control
- Case studies
- Perfusion monitoring & control strategy
- Mab DSP monitoring & control strategy

Margit Holzer, Scientific Director, **Ulysse Consult**, *Luxembourg*

12:30 *Lunch and Networking*

13:30 **Site Visit to Siemens, Living Lab Process Industries in Vienna**

*Both site visits are limited to 20 people. Places will be offered on a first come basis

18:00 *Return from Site Visit*

Microbial Manufacturing

8:30 Chairperson's Opening Remarks

8:35 This multi speaker symposium will focus on the latest developments and application of microbial based production (yeast and *E. coli*).

Some of the topics to be addressed through case study examples include:

- New Technologies for Primary Recovery and Cell Harvesting
- Downstream Processing in Microbial Production
- Automation, Robotics and High Throughput Process Development
- Developing a Roadmap to Perform Effective Scale Up in Microbial Manufacturing
- Developing and Validating Process Monitoring and Control Technologies for Robust Monitoring of Microbial Production
- Upstream Processing - Optimising Yield, Expression and Strain Development
- Adapting New Technologies and Equipment for Large Scale Microbial Production

Workshop Speakers:

Overcoming Scale-Up Challenges Through Effective Bioreactor Characterisation and the Use of Innovative Scale Down Model (SDM) Approaches

Richard Davies, Associate Director, Upstream Process Sciences, **UCB**, *UK*

Peter Neubauer, Laboratory of Bioprocess Engineering, **Technische Universität Berlin (TU Berlin)**, *Germany*

The Time has Come to Bring QbD to Inclusion Body Processing

Oliver Spadiut, Group Leader Integrated Bioprocess Development, **ICEBE**, **TU Wien**, *Austria*

Adapting New Technologies and Implementation of Single Use Systems

Ying Gao, Product Development Specialist, **Porton Biopharma Ltd**, *UK*

12:30 *Lunch and Networking*

13:30 **Site Visit to Boehringer Ingelheim, Regional Center, Vienna**

*Both site visits are limited to 20 people. Places will be offered on a first come basis

18:00 *Return from Site Visit*

MEET THE GLOBAL TECHNOLOGY LEADERS WHO CAN HELP YOU ENSURE PRODUCT SAFETY

SPONSORS



Exhibitors

(as of October 31, 2018)

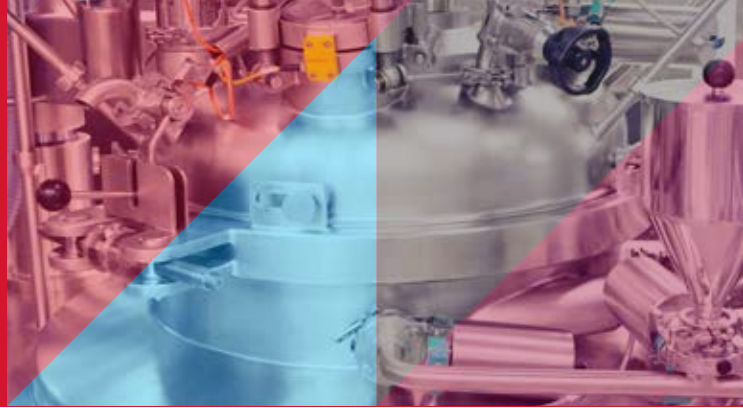
BlueSens
 Broadley James Ltd
 CerCell
 Cergentis
 Clean Cells
 c-Lecta GmbH
 Cygnus
 DrM
 em-tec
 EMP Biotech
 Eppendorf
 exputec
 Flownamics
 Huber Kältemaschinenbau AG
 Infors
 Irvine Scientific
 KAISER OPTICAL SYSTEMS
 Kaneka
 KBI
 Kerry
 Kuhner Shaker
 Labor Dr Merk
 Levitronix
 Novo Nordisk Pharmatech A/S
 PAIA Biotech
 Pendotech
 Pfanstiehl Inc.
 Presens
 Prometic
 PSG Dover/Almatec GmbH
 RSSL
 Saint-Gobain
 Secure Cell
 Shanghai Biological Science
 Stelis Biosource
 ViruSure
 Vögtlin Instruments GmbH

Sponsorship and Exhibition Opportunities

Contact Luke Pickering at +44 (0)20 3377 3553 or Luke.Pickering@knect365.com

<https://lifesciences.knect365.com/viral-safety/>

Stay Engaged Year-Round with **BioProcess International**

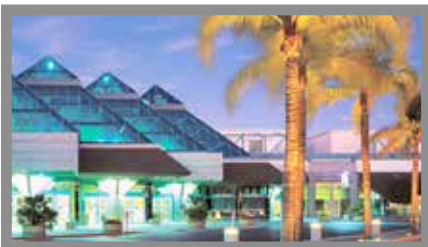


BioProcess International Asia

February 26-28, 2019

Tokyo, Japan

www.BioProcessAsia.com



BioProcess International US West

March 11-14, 2019

Santa Clara, California, USA

www.BioProcessWest.com



BioProcess International Europe

April 2-5 2019

Vienna, Austria

www.BioProcessEurope.com



BioProcess International

September 9-12, 2019

Boston, Massachusetts, USA

www.BPIevent.com



BioProduction

Part of

 **CPhI** worldwide®

November 5-7, 2019

Frankfurt, Germany

www.BioProductionEvent.com