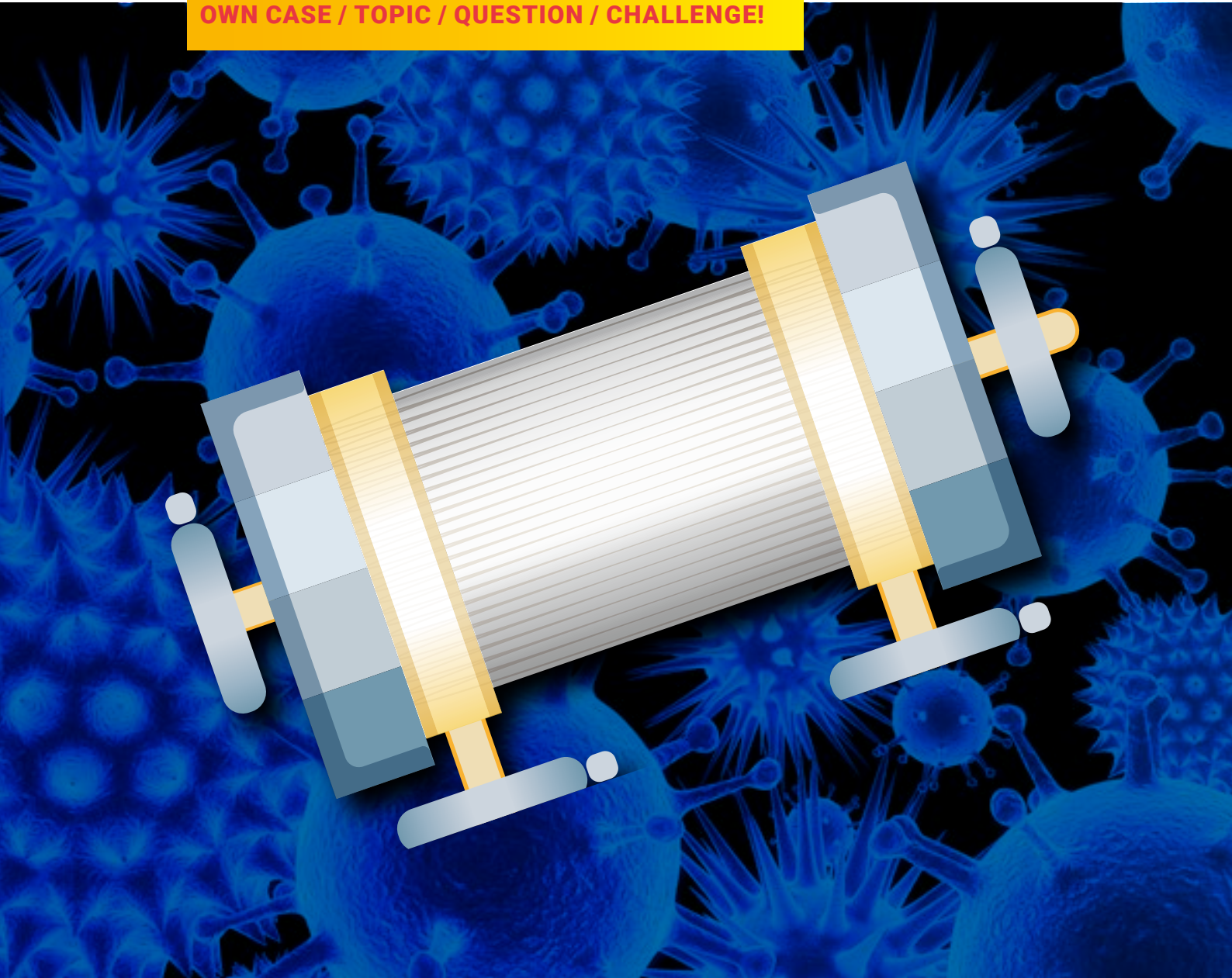


2019 PDA EUROPE TRAINING

All About Virus Filtration - A Practical Approach

**PARTICIPANTS ARE INVITED TO BRING THEIR
OWN CASE / TOPIC / QUESTION / CHALLENGE!**



10-11 SEPTEMBER 2019
ASAHI KASEI BIOPROCESS EUROPE
COLOGNE, GERMANY

WELCOME TO COLOGNE

All About Virus Filtration

A Practical Approach

Overview

This training course about virus filtration will provide the attendees with a profound understanding about the current state of the art around this topic. A thorough introduction to virus filtration will be given as well as in-depth background and a mechanistic understanding about the principles of (parvo-) virus retention will be available to the attendees at the end of the course. An interactive session will address the question of "how to design an efficient virus filtration process?" and a practical session will provide some hands-on experience with lab- and production-scale virus filter modules.

Who Should Attend:

- R&D scientists
- Supervisors in manufacturing
- QA Manager (Regulatory Affairs, Pathogen Safety)

Learning Objectives:

Upon completion of the course the participant

- have understood virus filtration principles
- ability to set-up and handle virus filtration processes
- have an overview of filter types and material
- have understood challenges of different matrices
- have gained hands-on experience with virus filters / process set-ups
- have understood principles/requirements of filter integrity testing
- have an overview of current guidelines and regulations



Sebastian B. Teitz, PhD, Product Manager & Scientific Coordinator, Asahi Kasei Bioprocess Europe

Sebastian Teitz graduated from University of Cologne with a diploma in Genomic Imprinting, followed with a PhD in the Analysis of O-glycosylated Proteins. Sebastian has previously worked at Fred Hutchinson Cancer Research Center (Seattle, WA), looking into Cytomegalovirus and its role in Graft vs. Host Disease and Transplant Rejection and at NewLab BioQuality / Charles River as the Project Manager of Virus Clearance Studies, focusing on scientific liaison with customers. At Asahi his focus lies with the technical, scientific and regulatory support of customers and internal entities, as well as representation in various industry organizations, such as the PDA, BPOG and CAACB.



Andy Bailey, CEO, ViruSure GmbH

Andy Bailey is a virologist who served for 9 years at the MRC Virology Unit in Glasgow. In 1995, he moved to the industry sector, initially as Director of Virus Validation services with Q-One Biotech Ltd, and later at the Pathogen Safety group of Baxter Healthcare in Vienna, Austria. Over the last 20 years Andy has been actively involved in the virus and prion safety field, presenting at numerous regulatory agencies either in support of products at the UK MHRA, German PEI, French AFFSAPS, US FDA, KFDA (Korea), EMEA and JMHLW (Japan) supporting regulatory submissions for various products. He has extensive experience in regulatory affairs and virus safety issues. Since 2005 he has been the founder and CEO of ViruSure in Vienna, Austria, a company specialising in the virus and prion safety of biopharmaceutical products



Franz Nothelfer, Consultant

Franz Nothelfer is consultant for downstream processing and viral safety. Before his retirement in 2017, he was heading a position as associate director Protein Science at Boehringer Ingelheim Pharma (BI), responsible for the development of novel purification processes for therapeutic proteins and monoclonal antibodies. A major task of his team was the transfer, establishment and optimization of purification processes of customers to achieve robust and economic manufacturing processes. Franz started his career in 1971 at Dr. Karl Thomae GmbH (later BI). In 1979 he joined the newly founded biotechnology department and was involved in the first process transfer of a recombinant protein to BI in 1985. During his career at Boehringer Ingelheim he took over several challenging positions.



Michael Lasse, PhD, Study Director Supervisor, Charles River Biologics Testing Solutions

Michael Lasse graduated from the University of Rostock with a diploma in Biology working on programmed cell death in neural progenitor cells. At the University of Cologne his PhD studies in Biochemistry focused on recombinant protein expression of apoptosis relevant membrane proteins, chromatographic purification techniques and post-translational lipid modifications. Michael Lasse joined Charles River as a study director for viral clearance studies and is currently supervising an operational team within the viral clearance department focusing on chromatography and related topics like continuous processing.

Tuesday, 10 September 2019**9:00 – 17:00**

9:00	Welcome and Theory 1 <ul style="list-style-type: none"> • Introduction into eukaryotic DS manufacturing process • Virus Filters in biopharmaceutical manufacturing • Sources of virus load • Reason/necessity for virus removal from DS • Virus realm • Sources of viruses • Examples of virus contaminations (plasma, biotech) • Outline of how to control the risk • Relevance of virus safety in ATMPs and potential applications 	Sebastian Teitz Andrew Bailey
10:50	Coffee Break	
11:20	Theory 2: Case Study <ul style="list-style-type: none"> • Up- & Downscaling of a virus filtration step 	Franz Nothelfer
12:50	Lunch Break	
13:50	Hands-on 1: Set-up and Handling of Filters <ul style="list-style-type: none"> • Set-up in lab-scale: hands-on • Display of production scale filters • Integrity tests: hands-on 	Sebastian Teitz
15:20	Coffee Break	
15:50	Theory 3: <ul style="list-style-type: none"> • Mechanistic principles of (Parvo-) Virus retention • Designing a virus filtration process – assumption and points to consider 	Sebastian Teitz
17:00	End of Day 1	
18:00	Networking Dinner	

Wednesday, 11 September 2019**9:00 – 15:30**

9:00	Wrap-up Day 1	All
13:50	Hands-on 2: <ul style="list-style-type: none"> • Set-up of filtrations with different protein solutions • Documentation 	All
10:30	Coffee Break	
11:00	Theory 4: <ul style="list-style-type: none"> • Introduction/background part for viral clearance - methods, guidelines • How to organize a virus clearance study • Challenges in VC studies • Historical data • Case studies for VC studies • Continuous manufacturing aspects in combination with virus filtration 	Michael Lasse
12:30	Lunch Break	
13:30	Revisit Filtration Results	Sebastian Teitz
13:30	Interactive session: Bring your own case/topic/question/problem/challenge for discussion! Participants have the opportunity to address real-life challenges during the implementation of a virus filtration process – from bench-top development through to commercial scale-up.	All
15:00	Wrap-up, Q&A	All
15:30	End of Course	

TRAINING LOCATION

Asahi Kasei Bioprocess Europe
Gottfried-Hagen-Strasse 20
51105 Cologne
Germany

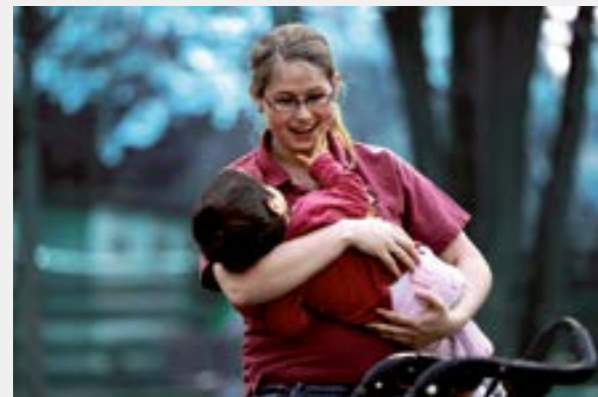
CONTACT INFORMATION

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registration-europe@pda.org

Education Program Inquiries
Elke von Laufenberg
training-europe@pda.org

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13507 Berlin, Germany
Tel: +49 30 436 55 08-0
Fax: +49 30 436 55 08-66



PDA Europe supports the children's hospice „Sonnenhof“

The Sonnenhof Hospice, located near PDA's office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases. At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering. Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy:

buy a package of chewing gums at the registration desk. THANK YOU!

To know more about the Sonnenhof Hospice, please visit www.bjoern-schulz-stiftung.de



3 WAYS TO REGISTER

- 1 online: pda.org/eu/VirusFiltration2019
- 2 FAX: +49 30 436 55 08-66
- 3 Email: registration-europe@pda.org

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

1 Your Contact Information

If this form is an update to a previously submitted form, please check here.

Mr. Ms. Dr. Nonmember I want to become a PDA Member.

PDA Member ID Number

Name (Last, First, MI) _____

Job Title _____

Company _____ Department _____

Mailing Address _____

City _____ Postal Code _____

Country _____ Email _____

Business Phone _____ Fax _____

Substituting for _____

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

2 Registration

All fees given in Euro, tax exempt in Germany

Two-Day Training Course (10-11 September 2019)
[All About Virus Filtration](#) **1595**

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

Your consent is important. We manage your personal data responsibly.
For more information, please visit pda.org/privacy-policy

RESPONSE REQUIRED – By checking the box(es) below, I consent to:

- My contact information (name, company, job title, city, state, country) being printed on the attendee list distributed at the event.
- PDA recording and/or photographing me and using those recordings and/or photographs in future PDA promotional and marketing materials.
- PDA sending me promotional information via email.
- PDA sending me promotional information via post

3 Payment Options

- By Credit Card**
- American Express MasterCard VISA

For your credit card information safety:
Please send your details by fax only (+49 30 436 55 08-66) or register online.

By Bank Transfer

Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDE33HAN
Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

By Purchase Order Purchase Order Number _____

PDA Europe VAT I.D.: VAT-Registration in Progress

Billing Address: Same as contact information address above. If not, please send your billing address to: registration-europe@pda.org

Your Company VAT I.D.: _____

This number starts by your country code with two characters
(example: PDA Europe's country code starts with: DE | followed by the number)

Date _____ Mandatory Signature _____

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A payment confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **11 August 2019** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at registration-europe@pda.org or fax to +49 30 436 55 08-66.

PDA EUROPE EVENTS



2019

2 September	Interest Group Meeting Freeze Drying	
2 September	Interest Group Meeting Technology Transfer	
3-4 September	BioManufacturing	★ Munich, Germany
5 September	Interest Group Meeting Vaccines	
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2 September	Interest Group Meeting Technology Transfer	
5 September	Project Management in the Pharmaceutical Industry	★ Munich, Germany
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24-25 September	Pharmaceutical Freeze Drying Technology	★ Berlin, Germany
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24-25 September	Particles in Injectables	★ Berlin, Germany
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21 October	Workshops:	
21 October	Innovating the Journey from Manufacturing to the Patient	
21 October	Innovative Drug Delivery Systems/Combination Products	★ Gothenburg, Sweden
21 October	Impact of Pre-filled Syringe Components on Biopharmaceuticals	
22-23 October	The Universe of Pre-filled Syringes and Injection Devices	
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12-13 November	Pharma Logistics & Outsourced Operations	
14 November	Interest Group Meeting Supply Chain Management	★ Lisbon, Portugal

2020

25-26 February	Parenteral Packaging	★ Basel, Switzerland
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21-22 April	Visual Inspection Forum	★ Berlin, Germany

Subject to change

For latest info: europa.pda.org

Shortlist 14 Aug 2019