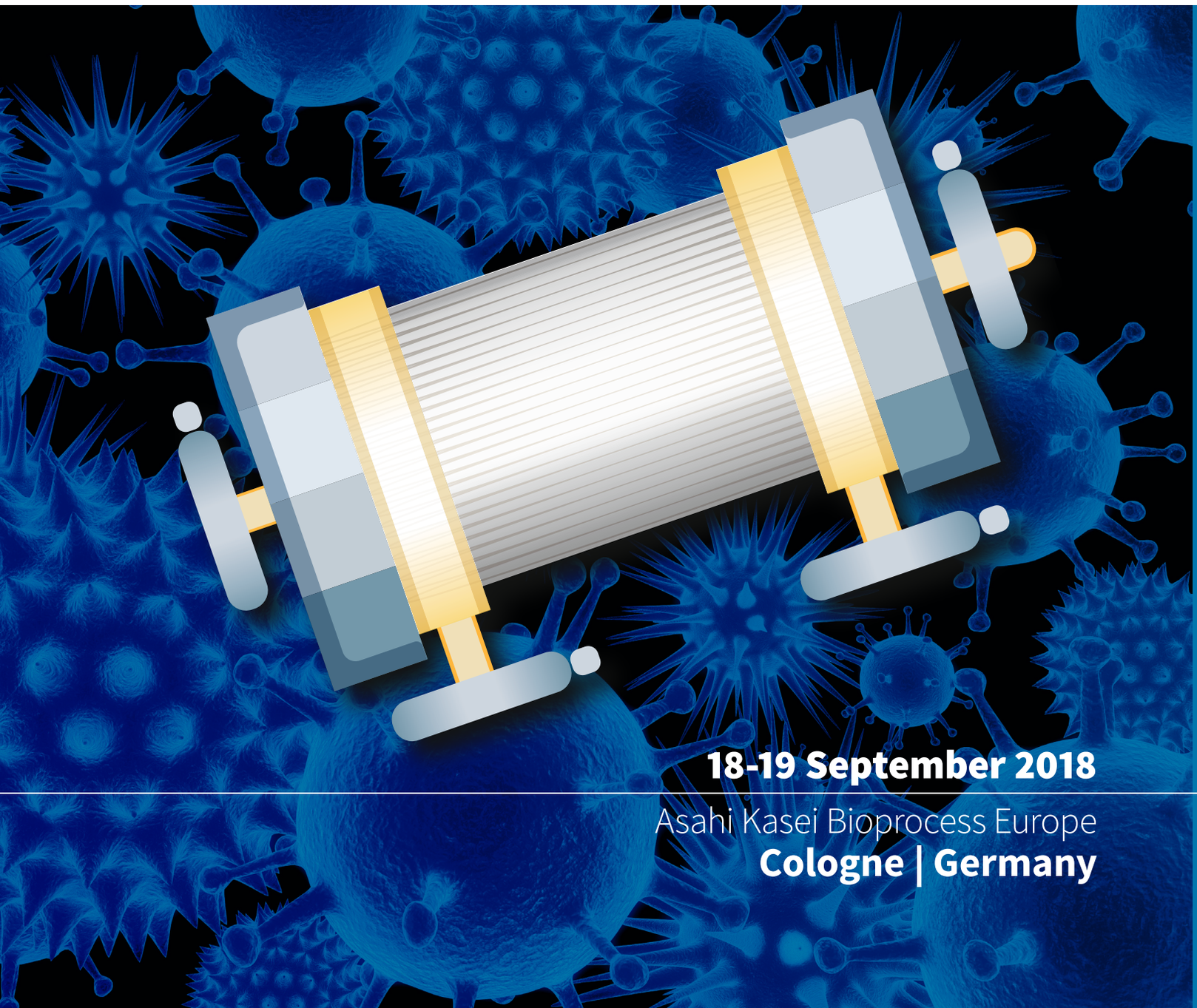
PDA Europe Training Course

The Parenteral Drug Association presents:

All About Virus Filtration

- A Practical Approach



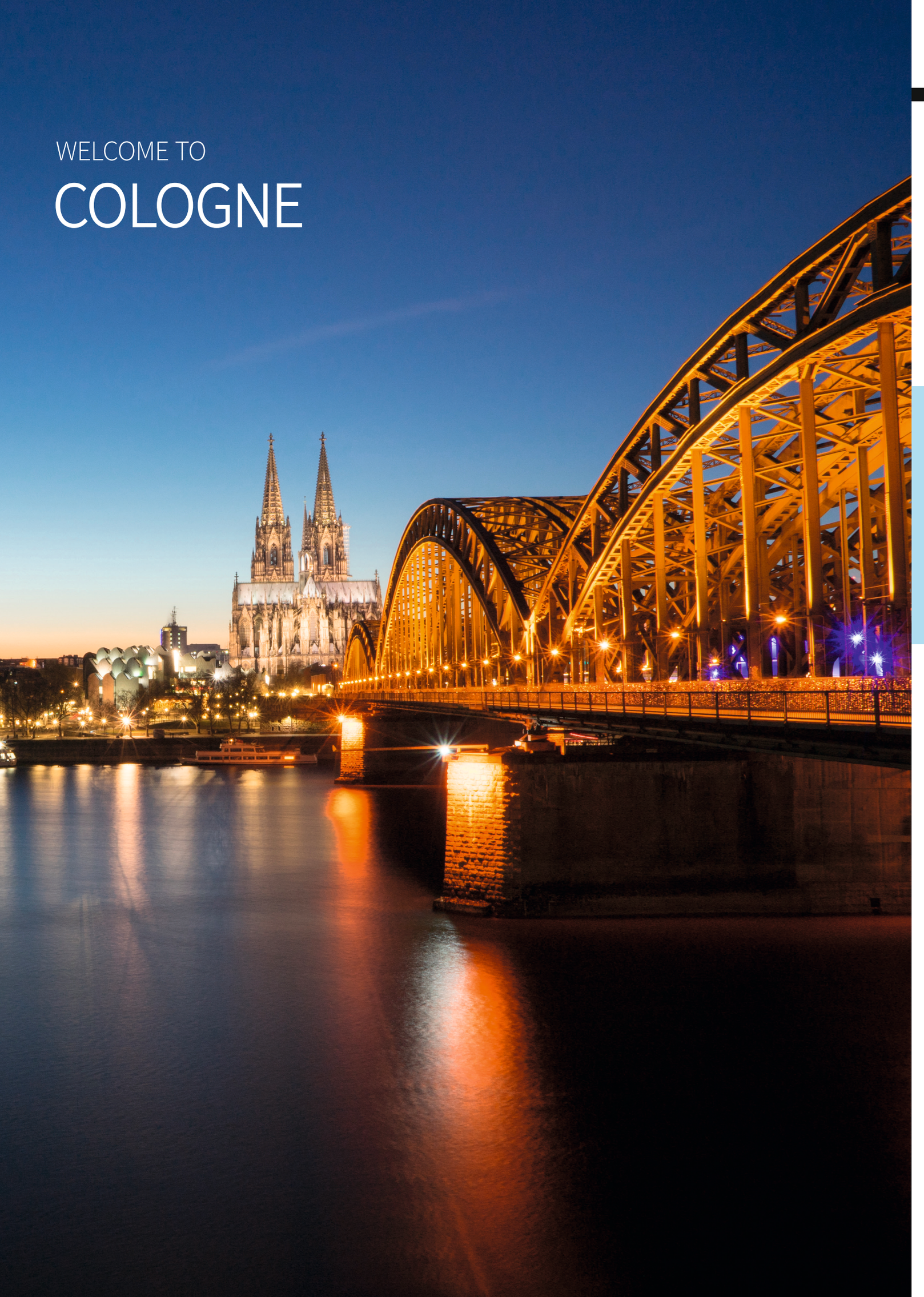
18-19 September 2018

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, Lab- & Product Manager, 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.

Competition Clause: We ask you for your understanding that participants of competing companies cannot take part in the training course.

Tuesday, 18 September 2018 — 8:30 – 17:00

8:30	**Welcome and Theory 1** • Introduction into eukaryotic DS manufacturing process • Virus Filters in biopharmaceutical manufacturing • Sources of virus load • Reason/necessity for virus removal from DS • Brief overview of guidelines • Methods for virus removal	Sebastian Teitz Andrew Bailey
10:00	**Coffee Break**	
10:30	**Hands-on 1: Set-up and Handling of Filters** • Set-up in lab-scale: hands-on • Display of production scale filters • Integrity tests: hands-on • Demonstration of integrity test automation	Sebastian Teitz
12:30	**Lunch Break**	
13:30	**Theory 2: Case Study** • Up- & Downscaling of a virus filtration step	Franz Nothelfer
15:00	**Coffee Break**	
15:30	**Interactive Session:** **Designing a virus filtration process – assumption and points to consider** • How to design a process • Calculating production costs	Sebastian Teitz
17:00	**End of Day 1**	
18:00	**Networking Dinner**	

Wednesday, 19 September 2018		8:30 – 15:30
8:30	**Wrap-up Day 1**	Sebastian Teitz
9:00	**Theory 4:** • Mechanistic principles of (Parvo-) Virus retention • Virus filters as bioprocess subject – current hot topics (ATMPS, facility segregation, etc.) • Challenges of implementing virus filtration into continuous manufacturing	Sebastian Teitz
10:30	**Coffee Break**	
11:00	**Theory 5:** • How to organize a virus clearance study • Challenges in VC studies • Historical data • Case studies for VC studies	Michael Lasse
12:30	**Lunch Break**	
13:30	**Interactive session:** **Pitfalls in the development of a virus filtration process** • 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 bencht-top development through to commercial scale-up.	Sebastian Teitz
15:00	**Wrap-up, Q&A**	Sebastian Teitz
15:30	**End of Course**	

TRAINING LOCATION

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

CONTACT INFORMATION

Registration Customer Care
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registration-europe@pda.org

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Elke von Laufenberg
training-europe@pda.org

GENERAL ADDRESS

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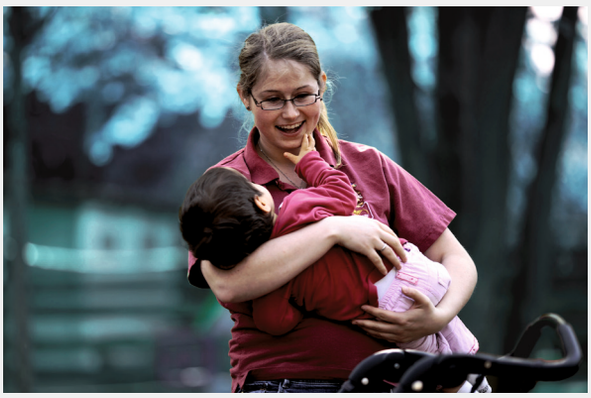

PDA Europe supports the children's hospice „Sonnenhof"

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**

Björn Schulz STIFTUNG
Für eine Zeit voller Leben

HOTELS NEARBY

PDA Europe recommends the reservation at one of the following hotels. The general terms of business are valid at the hotels.

Leonardo Hotel Köln
Waldecker Str. 11-15
51065 Cologne
Tel.: +49 (0)221 - 670 90
info.koeln@leonardo-hotels.com
https://goo.gl/PwRnR3

Price per Room and Night upon Request.
Distance to the venue: 2. 1 km (7 min by the car)

Pullman Hotel Cologne
Helenenstraße 14
50667 Cologne
Tel.: +49 (0)221- 2750
https://goo.gl/xrsX

Price per Room and Night upon Request.
Distance to the venue: 6. 3 km (19 min by the car)

All About Virus Filtration

18-19 September 2018 | Cologne | Germany

For contact at PDA Europe
registration-europe@pda.org

3 WAYS TO REGISTER

1. **ONLINE: pda.org/eu/VirusFiltration2018**
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.** Please send me a subsription form

☐ 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.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

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

Two-Day Training Course (18-19 September)
All About Virus Filtration

All Participants ☐ **1495**

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.

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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 4365508-66) or register online.

☐ **By Bank Transfer**

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

☐ **By Purchase Order** Purchase Order Number

PDA Europe VAT I.D.: DE254459362

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 letter of 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 **18 August 2018** 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 4365508-66. DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

2018 PDA EUROPE EVENTS

15-16 October	Pharmaceutical Microbiology	* Berlin, Germany
23-24 October	Visual Inspection Forum	* Berlin, Germany
6-7 November	Outsourcing & Supply Chain - A 360° View	* Seville, Spain
22 November	Project Management in the Pharmaceutical Industry – Challenges & Possibilities	* Berlin, Germany
27-28 November	Pharmaceutical Freeze Drying Technology	* Seville, Spain
27-28 November	11th Workshop on Monoclonal Antibodies	* Seville, Spain

2019 PDA EUROPE EVENTS

19-20 March	Parenteral Packaging	* Venice, Italy

Subject to change

For latest info: **europe.pda.org**

Shortlist 10 Jul 2018

*** Events with additional Education Program. More information – europe.pda.org**

PDA® Parenteral Drug Association

Connecting People, Science and Regulation®

General Information
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