

2019 PDA EUROPE TRAINING

Modern Polymer Pharmaceutical Packaging

WITH SITE VISIT AT BAUSCH + LOMB



22-23 MAY 2019

COURTYARD BY MARRIOTT BERLIN CITY CENTER
BERLIN, GERMANY





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BERLIN

Training & Education Program

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Modern Polymer Pharma Packaging

Overview

One of the main challenges in the pharmaceutical industry is selecting the most appropriate primary container system options covering a wide range from traditional glass containers to modern polymer container closure systems. Market segment range from generics to biotech, dosage forms from oral liquids to parenterals. This 2-day training course enables participants to evaluate different packaging systems for liquids and semi-liquids based on formulation properties, market requirements and end-user acceptability. The course is focused on polymer packaging materials and will provide an extensive overview about materials and systems, advantages and limitations. A brief comparison of polymer materials with glass is included in the course, as well as a detailed introduction to blow-fill-seal-technology including container closure integrity testing. Also, the different manufacturing and processes related to the implementation of polymer packaging materials will be discussed. Last but not least, most recent requirements, future trends and innovations in polymer pharmaceutical packaging will be outlined. The course combines classroom lectures with interactive exercises and discussions with experts in this field. The course will be completed with a site visit at a pharma facility, offering a special insight into aseptic blow-fill-seal processing.

Who Should Attend:

This course is designed for those involved in pharmaceutical development and manufacturing of drug products with responsibilities for selection of container closure systems:

- CMC experts
- Packaging development and engineering
- Formulation scientists
- Professionals in manufacturing and engineering

Pre-requisite to attend the course is an understanding of pharmaceutical development including basic primary packaging aspects. Specific knowledge and expertise in polymers is not required.

Learning Objectives:

Upon completion of this course attendees will be able to

- Develop target profiles for primary pharmaceutical packaging systems for liquids
- Understand modern pharmaceutical packaging technologies, materials, applications and requirements
- Compare different primary container systems with their advantages and limitations
- Understand the specifics of polymer materials used for primary packaging
- Evaluate the characteristics of manufacturing technologies for polymer packaging including blow-fill-seal technology
- Select packaging systems based on the evaluation of market requirements and drug product properties



Jörg Zürcher, Senior Scientist, Bayer

Jörg Zürcher is a pharmacist by education. After his studies and PhD thesis at the Free University in Berlin, he started his career in the pharmaceutical industry 1990 with the former Schering AG. He is responsible for the development of container closure systems and application devices at Bayer HealthCare and has more than 25 years' experience in that field. His current focus is the development of systems/devices for liquid and parenteral as well as ophthalmic dosage forms.



Michael W. Spallek, Director Research & Development, rommelag Engineering

Michael Spallek has over 25 years of professional experience that covers pharmaceutical packaging of different dosage forms from oral solids to parenterals and inhalable drug products including medical devices. Michael started his professional career at University of Karlsruhe receiving his PhD. in physical chemistry. He gained experience in medical grade materials from borosilicate glasses to high performance plastics in his role as director of the Pharma Competence Center of Schott AG. Previously he was responsible for global packaging development and Device development at Boehringer Ingelheim Pharma. Currently he is director of the R & D at rommelag, Germany Michael has published over 20 papers and holds several international patents in areas relating to coatings, devices and pharmaceutical packaging.



Bernd Zeiss, Head of Global Technical Support Medical Systems, Gerresheimer

Bernd Zeiss is biologist by education and graduated from the University of Göttingen, Germany. After several years working as a biostatistician, in lab automation and in pharma sales, he today is a member of the Gerresheimer business development team. He works in the Gerresheimer Centre of Excellence for pre-fillable syringes as Head of Technical Support Medical Systems. His main areas of work are technical customer support with regard to syringe systems as well as investigating possible interactions between syringe components and drug substance. He also evaluates innovations like COP syringes in comparison to glass and carries out inhouse functionality studies with prefilled syringes.

Competition Clause: We ask you for your understanding that participants of competing companies cannot take part in the Bausch + Lomb site visit on 23 May 2019.

Wednesday, 22 May 2019

9:00 – 17:00

9:00 **Welcome and Introduction**

9:15 **Target Product Profile and Container Closure System – From Drug to Packaging and Usability**

- Formulation
 - ▷ Compendial compliance
 - ▷ Properties e.g. viscosity
 - Processability
 - ▷ Aseptic filling
 - ▷ Thermal sterilization
 - Usability
 - ▷ User needs
 - ▷ Administration routes
 - ▷ Application systems
 - ▷ Single/multidose
 - ▷ Environmental conditions
-

9:55 **Primary Container Closure Systems, Part I: Bottles, Vials, Ampoules, Cartridges, Syringes**

- Requirements
 - Advantages and disadvantages
 - Overview about available systems
 - ▷ Glass (bottle, ampoules, vials, cartridges, syringes)
 - ▷ Polymers (vials, syringes)
-

10:15 **Primary Container Closure Systems, Part II: Blow-Fill-Seal Containers**

- Requirements
 - Advantages and disadvantages
 - Overview about available systems (external sources)
 - ▷ Bags
 - Overview about available systems (internal manufacturing)
 - ▷ Blow-fill-seal containers
 - ▷ Bottles
-

10:35 **Coffee Break**

11:05 **Basics of Blow-Fill-Seal Technology**

- From polymer granulates to filled and sealed containers
 - Traditional BFS-process
 - Multilayer options
-

11:35 **Interactive Exercise 1:**

Impact of drug formulation and application on primary packaging and container closure system

12:30 **Lunch Break**

13:30 Dosage Forms, Designs and Usability of BFS Containers

- Ophthalmics
- Inhalation
- Parenterals
- Terminal sterilization
- User acceptance and usability
 - ▷ Optimized application of infusions
 - ▷ Easy empty containers

14:00 Recent Innovations in Blow-Fill-Seal

- Cool-BFS for temperature sensitive formulations
- Increased functions by inserted parts
- Adapters/closures for minimizing administration errors and increasing safety

14:30 Coffee Break

15:00 Interactive Session 2:

Impact of drug formulation and application on selection of primary packaging and container closure system and on manufacturing of primary packaging

16:30 Summary Day 1 and Q & A

17:00 End of Day 1

Thursday, 23 May 2019

9:00 – 17:15

09:00 Primary Packaging Materials, Part I: Glass, Polymers

- Glass
 - ▷ Glass types
 - ▷ Basic properties
 - ▷ Advantages, limitations
 - ▷ Novel compositions, trends
 - ▷ Manufacturing
 - Tubing
 - Converting
 - Molding
 - Surface treatment
- Polymers
 - ▷ PE, PP, COP/COP
 - ▷ Basic properties
 - ▷ Advantages, limitations
 - ▷ Trends
 - ▷ Manufacturing
 - Molding
 - Surface treatment

9:40 Primary Packaging Materials, Part II: Elastomers

- Elastomers
 - ▷ Butyl, halobutyl, synthetic polyisoprenes, SBRs
 - ▷ Basic properties
 - ▷ Advantages, limitations
 - ▷ Trends
 - ▷ Manufacturing
 - Surface treatment

TWO-DAY TRAINING COURSE

10:00	Coffee Break
10:30	Practical Considerations During Development/Selection of Packaging System <ul style="list-style-type: none">• Interaction of packaging materials with drug product• Closure system• Impact of storage/transportation temperatures• Container closure integrity test methods
11:30	Interactive Session 3: Risk Analysis of material selection (glass or COC/COP) for pre-filled syringes during development of new biopharmaceutical drug product
12:30	Lunch Break
13:15	Bus Transfer to Bausch + Lomb
14:00	Introduction to Facility Tour <ul style="list-style-type: none">• "Virtual" tour through facility: what will be seen• Different type of BFS technology• CCIT• Inspection systems
14:30	Facility Tour at Bausch + Lomb <ul style="list-style-type: none">• BFS machines types in production• CCIT in operation• Inspection systems in operation
15:30	Summary Day 1 & 2 and Q & A
16:00	Farewell Coffee
16:30	Transfer to Training Course Hotel
17:15	End of Training Course

2019 PDA EUROPE

The Universe of Pre-filled Syringes and Injection Devices

Advancing Drug Delivery Systems to Improve Patients' Lives



22-23 OCTOBER 2019

GOTHENBURG, SWEDEN

PRE-CONFERENCE WORKSHOPS: 21 OCTOBER

CONFERENCE & EXHIBITION: 22-23 OCTOBER

EDUCATION & TRAINING: 24-25 OCTOBER

MARK YOUR CALENDAR

VENUE

Courtyard by Marriott Berlin City Center

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Berlin 10117
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CONTACT INFORMATION

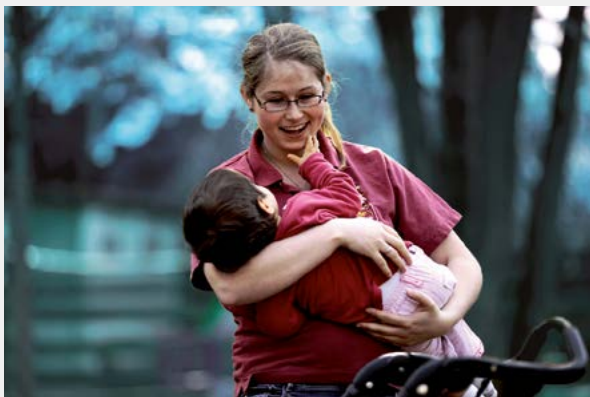
Registration Customer Care

Tel: +49 30 436 55 08-10
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Education Program Inquiries

Elke von Laufenberg

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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



Für eine Zeit voller Leben

3 WAYS TO REGISTER

- 1 online: pda.org/EU/PMP19
- 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

Competition Clause:
 We ask you for your understanding that participants of competing companies cannot take part in the Bausch + Lomb site visit on 23 May 2019.

All fees given in Euro, tax exempt in Germany

Two-Day Training Course (22-23 May 2019)
 Modern Polymer Pharmaceutical Packaging 1595

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

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 Please send your details by fax only (+49 30 436 55 08-66) or register online.

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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

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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 **21 April 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.

2019 PDA EUROPE EVENTS

18 March 19-20 March 21 March	Interest Group Meeting Pre-filled Syringes Parenteral Packaging Interest Group Meeting Packaging Science	★ Venice, Italy
16-17 May	Pharmacopoeia	★ Geneva, Switzerland
22-24 May 24 May	Visual Inspection Week Interest Group Meeting Visual Inspection	★ Berlin, Germany
4-5 June	Advanced Therapy Medicinal Products	★ Vilnius, Lithuania
24 June 25-26 June	Interest Group Meeting Quality Systems 4th PDA Europe Annual Meeting	Amsterdam, The Netherlands
3-4 September	BioManufacturing	★ Munich, Germany
5 September	Project Management in the Pharmaceutical Industry	★ Munich, Germany
24-25 September	Pharmaceutical Freeze Drying Technology	★ Berlin, Germany
24-25 September	Particles in Injectables	★ Berlin, Germany
22-23 October	The Universe of Pre-filled Syringes and Injection Devices	★ Gothenburg, Sweden
12-13 November	Outsourcing & Supply Chain	★ Lisbon, Portugal

Subject to change

For latest info: europe.pda.org

Shortlist 12 Dec 2018

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

