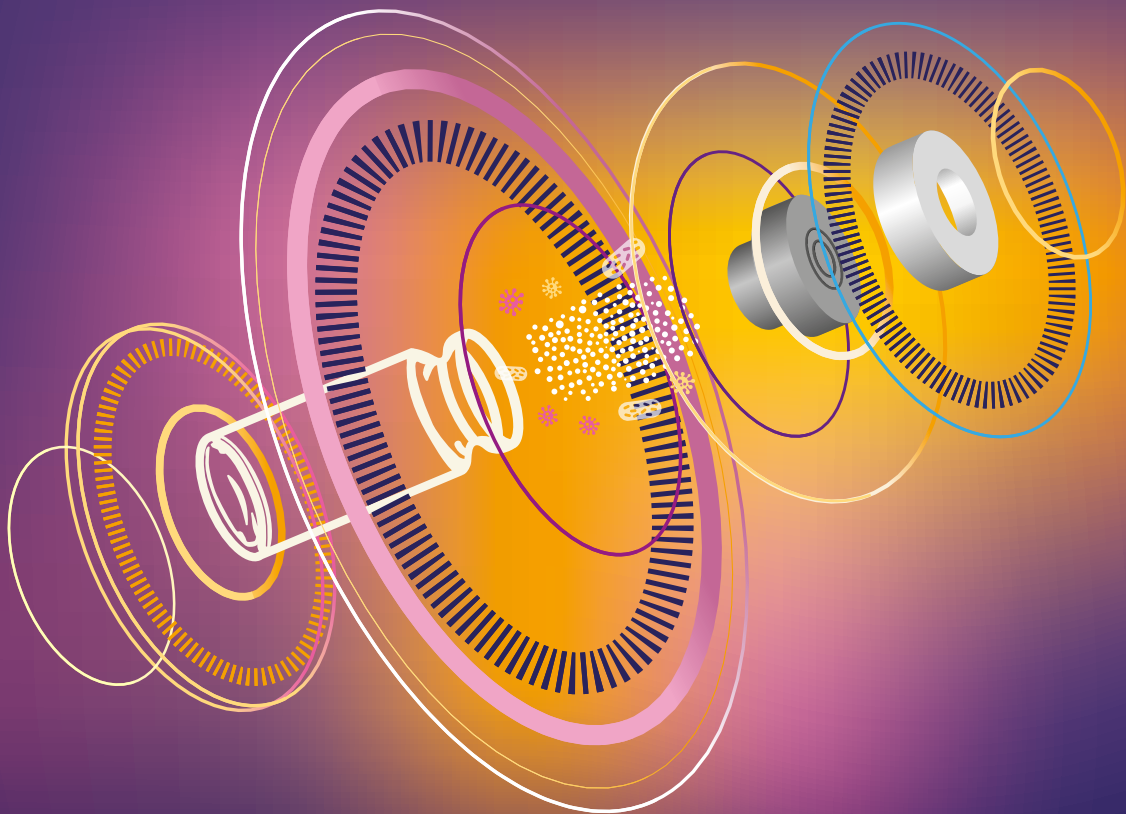


2020 PDA EUROPE

Parenteral Packaging

CALL FOR ABSTRACTS



25-26 FEBRUARY 2020

BASEL, SWITZERLAND

EXHIBITION: 25-26 FEBRUARY

TRAINING COURSES: 27-28 FEBRUARY

IG MEETINGS: 24+27 FEBRUARY

ABSTRACT SUBMISSION DEADLINE: 27 SEPTEMBER 2019

CONFERENCE OVERVIEW

Dear Colleague,

We would like to invite you to submit a paper or poster abstract for presentation at the
PDA Europe Parenteral Packaging Conference, 25-26 February 2020 in Basel, Switzerland!

Abstracts must be non-commercial in nature, describing new and innovative developments or work that significantly contributes to the body of knowledge relating to primary and secondary packaging of parenteral drugs and all related aspects as stated below.

The Program Planning Committee will review all proposals carefully and consider podium and poster contributions.

We look forward to receiving your topic proposal!

Sincerely,

The Co-Chairs



Roman Mathaes,
Lonza, Chair



Galen Shi,
Eli Lilly, Chair

Call for Abstracts

Topics areas of interest will include but are not limited to:



1. REGULATORY UPDATES

- ISO Standard Series ISO 11608 on Needle-based Injection Systems, Updates on ISO Technical Committees TC76 and TC84
- New Regulations from Agencies, Pharmacopoeia & Industry Perspectives with a Special Interest in Updates from China, India, and Japan
- USP <381>, <660>, <661>, <1207>, <1660>, <1663>, <1664>, <790> and <1790>
- Pharm. Eur. 3.1, 3.2 and 3.3
- Updates on PDA Technical Reports 27, 43, 73, 76 and 77
- Update on FDA 1999 Container Closure Guidance
- FDA Updates for Cell & Gene / ATMPs Therapies
- FDA Guidance on Safety Considerations for Product Design
- Impact of Post-Approval Regulatory Requirement Changes on Products
- ICH Q3D - Elemental Impurities and their Application to Packaging Materials
- Annex 1 Revision



2. CONTAINER CLOSURE INTEGRITY (CCI)

- The Role of CCI in Product-Package Development
- The Role of CCI in Post-Approval Product Changes
- CCI in Routine Manufacturing
- CCI for API Storage Containers and Single Use Equipment & during shipping
- CCI for Complex Combination Products
- CCI Testing vs. CCI Control Strategy in Manufacturing
- CCI Testing as Part of Post-Approval Processing Changes
- Coherent CCI Testing Strategy across the Product Life Cycle
- Test Methods, On-line vs. Off-line Testing
- Simulation Work, Failure Modeling
- Modeling of Artificial Leaks
- Modeling of Process Unit Operation Impact on CCS Components
- Product Release Specification vs. Internal Quality Criterion
- Approaches & Solutions for Cryogenic Storage



3. QUALITY OF COMPONENTS & CONTAINERS – DESIGN, MATERIALS, NEW TECHNOLOGIES

- Glass and Other Packaging Materials, Defects and Categorization
- Surface Modified Materials
- Alternative Container Closure Systems
- Polymers/Elastomers
- Large Volumes, Bags
- Blow-Fill-Seal
- Stoppers, Caps, Labels
- API-Surface Interaction
- Extractables & Leachables Studies
- Supplier Issues
- Anticipating and Managing Post-Approval Component Changes
- Anti-Counterfeiting
- Simulation Work
- Container Closure System Qualification (for human use)
- Particulate Cleanliness
- End-User Preferences - Usability & Handling

SCIENTIFIC PROGRAM PLANNING COMMITTEE

- Roman Mathaes**, *LONZA, Chair*
- Galen Shi**, *Eli Lilly, Chair*
- Roger Asselta**, *Genesis Packaging Technologies*
- Bettine Boltres**, *WEST*
- Derek Duncan**, *LIGHTHOUSE*
- Robert Guidos**, *Corning*
- Renaud Janssen**, *Datwyler*
- Philippe Lauwers**, *Terumo*
- Yusuf Oni**, *Bristol-Myers Squibb*
- Robert Ovidia**, *Genentech*
- Herve Soukiassian**, *BD*
- Folker Steden**, *SCHOTT*
- Joerg Zuercher**, *Bayer*
- Kerstin Wilken**, *PDA Europe*
- Teresa Schubach**, *PDA Europe, Manager Programs & Events*



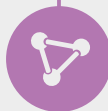
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 MCH Messe Schweiz (Basel) AG
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 Fax: +41 58 206 21 86
 info@congress.ch
 www.congress.ch

t limited to the following



4. PROCESSING AND PRODUCT DISTRIBUTION/STORAGE

- Glass Handling and Reduction of Breakage
- Formulation & Fill-finish Operations
- Lyophilization
- Stoppering, Sealing, Capping, Crimping Operations
- Reduction of Variability during Capping
- Influence of Stopper Permeability on the Headspace of Sterile Vials during Storage
- Visual Inspection: Container-linked Particles
- Managing Processing Changes in a dynamic post-approval world
- Challenges in Shipping, Distributio & Last-Mile Distribution
- Integrity and (Statistical) Risk Assessment
- Addressing the User Interface via Packaging
- Solutions Addressing the FDA Guidance on Safety
- Considerations on Product Design to Minimize Medication Errors
- Managing Processing Changes
- Primary & Secondary Packaging
- Serialization
- CSTDs and primary packaging
- Ophthalmic applications
- Challenges for CMOs



5. FORMULATION-PACKAGING INTERACTIONS

- Silicon Oil Interactions
- Incompatibilities with Leachables from Glass/Elastomers
- Rubber Components leading to Drug Product Degradation
- Fogging
- Delamination



6. ASEPTIC PROCESSING

- Sterilization
- Handling
- Test Methods
- New Technologies

PDA Submission Process

THE ONLINE PROCESS ASKS YOU TO PROVIDE THE FOLLOWING INFORMATION:

- PRESENTATION TITLE
- PRESENTER'S NAME AND CONTACT DETAILS
- PRESENTER'S BIOGRAPHY (APPROX. 100 WORDS)
- ADDITIONAL SPEAKERS (IF APPLICABLE)
- KEY OBJECTIVES OF TOPIC
- 2-3 PARAGRAPH ABSTRACT, SUMMARIZING THE TOPIC

All submitted abstracts will be reviewed by the Scientific Program Planning Committee for acceptance. PDA Europe will provide one complimentary registration per podium presentation. Additional presenters and poster presenters are required to pay appropriate conference registration fees. Abstracts not selected for a 30-minute podium presentation may be invited to join as a scientific poster contribution.

Please click or scan the QR Code to submit your abstract.



<https://bit.ly/2RSxRLL>

Deadlines

Abstracts for Podium Presentation: **27 September 2019**

Printfile for Poster Session: **10 January 2020**

If you have any further questions, please do not hesitate to contact programs-europe@pda.org

To Exhibit:

PDA is seeking vendors who provide products / services in support of this conference.

Space is limited and is on a first-come, first-serve basis. To reserve your space, please contact, expo-europe@pda.org or via telephone +49 30 436 55 08 23.

PDA Scientific Poster Presentation

Exhibit Your Work

Deadline:
10 January 2020



To join our scientific poster session, the poster has to be non-commercial in nature. Please send a printable PDF file according to the following specifications:

Canvas size to work on:

85 cm x 120 cm (33,465 x 47,244 in) – portrait format
Slug / Bleed: 2 mm (0,079 in)

Images:

120dpi (low) - 150dpi (high) depending on size.
All Images Color Profile ISO Coated v2 (ECI)

Document size of the PDF:

85 cm x 206 cm (33,465 x 81,102 in) – portrait format
Slug / Bleed: 2 mm (0,079 in)

All posters will be printed by PDA and displayed as part of the exhibition.

Poster Display is included in the regular conference registration fee. Please send your file and poster title to Christopher Haertig expo-europe@pda.org.

25-26 February 2020 | Basel | Switzerland

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

Your registration is only complete upon filling in and submitting both pages of this form.

1 Registration

EARLY BIRD DISCOUNT

Book by 27 Dec 2020 to receive € 200 off the conference fee only

All fees given in Euro, excluding VAT (7,7 %)

25-26 February 2020

Conference

Conference Fee

Parenteral Packaging

PDA Member **1895**

¹Nonmember **2195**

²Young Professionals **950**

Early Bird 750 € ¹Regulatory/Academic **950**

Poster Presenter please mark here (written approval required, conference fee applies)

24 February IG Meeting Pre-filled Syringes	Interest Group Meeting	Training Course Fee All Participants <input type="checkbox"/> 350
27 February IG Meeting Packaging Science	Interest Group Meeting	Training Course Fee All Participants <input type="checkbox"/> 350
27 February Container Closure Development	One-Day Training Course	Training Course Fee All Participants <input type="checkbox"/> 895
27-28 February Container Closure Integrity Testing	Two-Day Training Course	Training Course Fee All Participants <input type="checkbox"/> 1595
27-28 February CCIT for the Advanced User	Two-Day Training Course	Training Course Fee All Participants <input type="checkbox"/> 1595
27-28 February Extractables and Leachables	Two-Day Training Course	Training Course Fee All Participants <input type="checkbox"/> 1595

My contact information (name, company, job title, city, state, country) being printed on the attendee list distributed at the event.

PDA sending me promotional information via email.

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 post

The fee includes event 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.

Registration fee includes a one-year PDA membership if no further special discount is granted. If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies).

² Rate applicable to all professionals 30 years of age or younger. A proof via ID or Passport copy is required, please submit this via fax or e-mail. Rate does not include membership. Further discounts as of Early Bird and Group Discount are not applicable to this rate.

Group Registration Discount Register 3 colleagues for the conference at the same time and receive the **4th registration free**. Other discounts cannot be applied. For more information on group discounts please contact at registration-europe@pda.org.

Discount for Exhibiting Companies

Please mark here if your company is an exhibitor to this event and you will receive the conference ticket at the **special price of 1195 € per ticket**. No further discounts are applicable with this option (as PDA Membership Discount or Group Discount).

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

25-26 February 2020 | Basel | Switzerland

3 WAYS TO REGISTER

- 1 online: pda.org/EU/ParPack2020
- 2 FAX: + 49 30 436 55 08-66
- 3 Email: registration-europe@pda.org

2 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 subscription 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.)

3 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).

4 Payment Options

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 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 Purchase Order

Purchase Order Number _____

Billing Address: Same as contact information address above.
 If not, please send your billing address to: petzholdt@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)

PDA Europe VAT I.D.: DE254459362

Your registration is only complete upon filling in and submitting both pages of this form.

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 **27 January 2020** 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

24-25 September **Pharmaceutical Freeze Drying Technology** ★ **Berlin, Germany**

24-25 September **Particles in Injectables** ★ **Berlin, Germany**

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**

12-13 November **Pharma Logistics & Outsourced Operations** ★ **Lisbon, Portugal**
14 November Interest Group Meeting Supply Chain Management

2020

25-26 February **Parenteral Packaging** ★ **Basel, Switzerland**

21-22 April **Visual Inspection Forum** ★ **Berlin, Germany**

Subject to change

For latest info: europa.pda.org

Shortlist 19 Aug 2019