

2022 PDA



PARENTERAL PACKAGING CONFERENCE

PREPARING FOR THE FUTURE:
INNOVATING PACKAGING TECHNOLOGIES

pda.org/EU/2022ParPack

02-03 JUNE 2022

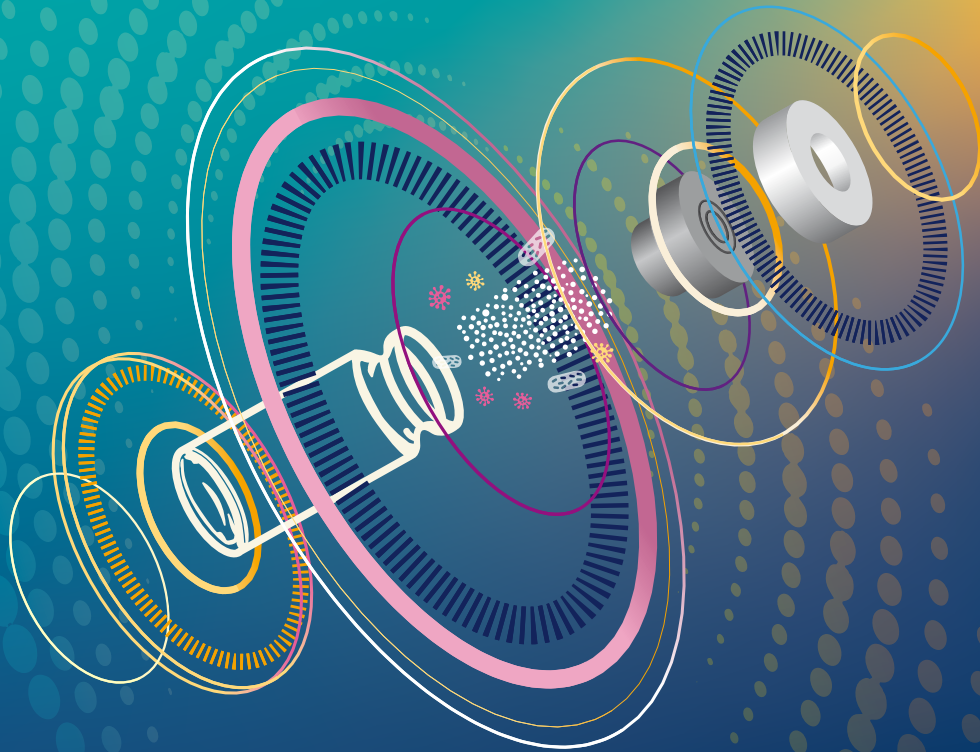
BASEL, SWITZERLAND

EXHIBITION: 02-03 JUNE

TRAINING: 31 MAY – 01 JUNE

WORKSHOPS: 01 JUNE

**REGISTER BEFORE 03 APRIL
AND SAVE UP TO €200!**



CONNECTING
PEOPLE
SCIENCE AND
REGULATION®

WELCOME FROM THE CHAIRS

Dear Colleagues,

On behalf of the Scientific Program Planning Committee and PDA, we are proud to invite you to the **12th Parenteral Packaging Conference** to take place in **Basel/Switzerland, 02-03 June**.

New technologies and materials are arising and known challenges are being addressed with new techniques, not only due to the pandemic and its consequences. This Conference has traditionally seen a strong mix of representatives from large pharmaceutical companies, packaging component vendors, leaders in manufacturing equipment, and regulatory experts. This enticing mix of delegates provides for a well-rounded conference agenda with top-notch presentations and interactive discussions around the complete pharmaceutical packaging value chain.

Packaging development for parenteral preparations cannot be discussed as an isolated activity. Instead, a holistic and integrated approach considering the relevant development interfaces is inevitable. Drug-container interactions are a topic that always provokes new studies and discoveries, e.g., focusing on drug adsorption onto the primary container components' surfaces or the impact of siliconization on prefilled syringe functionality.

This year's conference has a specific focus on innovation with dedicated track sessions on advanced packaging solutions and traceability. In the light of the current global situation, cold storage received unexpectedly strong attention and will also have its place in the program. As the regulatory landscape is evolving constantly, we will continue placing a focus on updates on regulatory changes. Finally, we will introduce sustainability along with the pharmaceutical packaging and filling value chain as a new strong agenda topic.

Join the PDA packaging community from all over the world and the involved parties, such as pharma companies, large and small, component suppliers, system suppliers, filling line vendors, analytical service providers, global regulators, and start-ups, just to name a few.

Ample exchange will be fostered during lunch and coffee breaks, interactive side events, and exciting evening networking activities. Meet old friends and gain new ones at the long-awaited return to the on-site format in beautiful Switzerland! Basel features not only some of the most important European Pharma hubs with headquarters of Roche and Novartis but also a flourishing Biotech startup ecosystem.

We are much looking forward to meeting you once again at the 2022 Parenteral Packaging Conference!

Sincerely,
The Chairs



Bettine Boltres,
WEST



Roman Mathaes,
Lonza

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Bettine Boltres, *WEST, Chair*

Roman Mathaes, *Lonza, Chair*

Roger Asselta, *Auxilium Packaging Advisors*

Derek Duncan, *LIGHTHOUSE Instruments*

Robert Guidos, *Corning*

Bram Jongen, *Datwyler*

Philippe Lauwers, *Terumo*

Robert Ovidia, *Genentech*

Galen Shi, *Eli Lilly & Company*

Folker Steden, *SCHOTT*

Jörg Zürcher, *Bayer*

Ankur Kulshrestha, *Bristol-Myers Squibb*

Janie Miller, *PDA*

Falk Klar, *PDA*

Stefanie Nebelin, *Manager Programs & Events, PDA*

WELCOME TO PARENTERAL PACKAGING CONFERENCE



COVID-19 PERSONAL PRECAUTIONARY MEASURES

PDA is committed to deliver safe and secure in-person events. In conjunction with the venue and vendors supporting our event, PDA strictly adheres to all national, provincial and local government regulations.

THURSDAY, 02 JUNE 2022

09:00 – 18:00 CEST

9:00 Welcome and Introduction

Falk Klar, *PDA*
Roman Mathaes, *LONZA*
Bettine Boltres, *WEST*

OPENING PLENARY: A Status Update from the Parenteral Packaging Industry

Moderator: Roman Mathaes, LONZA

Hear the opening keynote presentation about innovation in the primary packaging ecosystem and an update of the regulatory landscape around the globe.

Opening Keynote: Parenteral Packaging: Big Picture Trends in Pharma *Roche*

Regulatory Perspectives on Sterile Drug Packaging Quality *Consultant for the U.S. FDA*

Pharma Manufacturing Wish List for Primary Containers *Pfizer*

10:45 COFFEE BREAK, POSTER SESSION & EXHIBITION

Manufacturing of Pandemic Vaccines – Manufacturing Solutions Enabling the Delivery of Large Numbers of Vaccine Doses *CEPI/COVAX*

Introducing PDA TR 87 *Bettine Boltres, WEST*

Interactive Questionnaire Session

12:15 Q&A, Panel Discussion *Moderator: Roman Mathaes, LONZA*

13:00 LUNCH BREAK, POSTER SESSION & EXHIBITION

| SESSION 1: | TRACK A | TRACK B |
|------------|---|--|
| | <p>Advancing Packaging Solutions <i>Moderator: Roger Asselta, Auxilium Packaging Advisors</i></p> <p>This session will explore three solutions mitigating glass breakage issues. From advanced coatings to innovating labels, to unique vial packaging. These solutions, come from innovators from around the world, use different approaches to face a universal challenge.</p> | <p>Traceability <i>Moderator: Galen Shi, Eli Lilly & Company</i></p> <p>Next-generation container closures and delivery devices call for consideration of digital tracking capability such as unit-level traceability. This would provide benefits in preventing product mix-up, identification of product lots implicated with quality issues, as well as anti-counterfeiting.</p> |
| | <p>Evaluation of the Utility of Vial Packaging to Reduce Occupational Exposure to Antineoplastic Drugs in Preventing Breakages and Scattering <i>Tohoku University on behalf of Iwata Label</i></p> | <p>Unit Level Syringe Identification & Traceability <i>BD</i></p> |
| | <p>How Can the Choice of Label Positively Impact the Sustainability and Recyclability of Pharmaceutical Packaging <i>UPM Raflatac</i></p> | <p>Medical Device Tracking - Seamless Traceability for Maximum Patient Safety <i>Uhlmann</i></p> |
| | <p>Assessment of Coating Effect on Vial Crack Response <i>Corning Incorporated</i></p> | <p>Delivering Unit Level Process Visibility in Parenteral Fill-Finish and All Other Manufacturing Processes <i>Optima & Eagas</i></p> |
| | <p>Q&A, Discussion <i>Moderator: Roger Asselta, Auxilium Packaging Advisors</i></p> | <p>Q&A, Discussion <i>Moderator: Galen Shi, Eli Lilly & Company</i></p> |

16:00 Coffee Break, Poster Session & Exhibition

| SESSION 2: | TRACK A | TRACK B |
|------------|--|---|
| | <p>Drug Administration <i>Moderator: Ankur Kulshrestha, BMS</i></p> <p>Session featuring presentation and case study highlighting the interaction of drug product with CSTDs and enabling drug administration at home using vial adaptors.</p> | <p>Fill & Finish / Manufacturing <i>Moderator: Bram Jongen, Datwyler</i></p> <p>Don't let your fill & finish be the weakest link in the supply chain! Gain more insights into today's challenges of the different primary packaging configurations and see how the future can look like using No Touch Transfer concepts!</p> |
| | <p>Impact of CSTDs on Administered ADC Quality <i>Merck KGaA</i></p> | <p>Primary Packaging Container and Handling During Fill & Finish Processes <i>Swissfillon – a Ten3 Health Company</i></p> |
| | <p>Development of a Vial Adapter for Home Use: A Case Study <i>Roche</i></p> | <p>End-To-End Qualification of Ready to Use (RTU) Product Containers in Packaging Suitable for NTT: No-Touch-Transfer into Grade A Filling Zones <i>Franz Ziel</i></p> |
| | <p>Q&A, Discussion <i>Moderator: Ankur Kulshrestha, BMS</i></p> | <p>Q&A, Discussion <i>Moderator: Bram Jongen, Datwyler</i></p> |

18:00 END OF CONFERENCE DAY 1 & NETWORKING EVENT



CONFERENCE AGENDA

FRIDAY, 03 JUNE 2022

09:00 – 16:30 CEST

| SESSION 3: | TRACK A | TRACK B |
|------------|---|---|
| | <p>Primary Container Selection for Specific Products <i>Moderator: Robert Guidos, Corning Incorporated</i></p> <p>Choosing the right packaging is critical to protecting a drug product's identity, strength, purity, quality, and safety. Come join us as we continue to understand interactions between drug products and specific packaging types and how such understanding can help guide package selection.</p> | <p>Cold Storage <i>Moderator: Folker Steden, SCHOTT</i></p> <p>Large molecule temperature-sensitive pharmaceuticals often require high-tech equipment and packaging material for cold storage to prevent them from disintegration. A so-called cold chain is needed – A temperature-controlled supply chain, which is required to preserve and maintain perishable pharmaceutical products. Join our session to learn more about the impact on different materials (glass, organics) and the resulting chemical properties of these materials at low and very low storage temperatures.</p> |
| | <p>Case Study: Protein Adsorption /Aggregation on Glass and Polymer Surfaces <i>WEST</i></p> | <p>Influence of Freezing Storage Condition on Glass Syringe Performance <i>Stevanato Group</i></p> |
| | <p>Pre-filled Syringe Silicone Loading: Quantifying the Functional Impact of Homogeneity Variations <i>SCHOTT</i></p> | <p>Low-Temperature Storage Extractables and Leachables Considerations <i>Sartorius Stedim</i></p> |
| | <p>Q&A, Discussion <i>Moderator: Robert Guidos, Corning Incorporated</i></p> | <p>Q&A, Discussion <i>Moderator: Folker Steden, SCHOTT</i></p> |

10:30 COFFEE BREAK, POSTER SESSION & EXHIBITION

| SESSION 4: | TRACK A | TRACK B |
|------------|---|---|
| | <p>Container – Drug Interactions <i>Moderator: Robert Ovadia, Gilead</i></p> <p>Come join us as we learn about selecting the appropriate container material for complex drug product formulations in order to reduce potential drug-container interactions. We'll cover mRNA-based, lyophilized, and high pH drug product formulations.</p> | <p>Container Closure Integrity <i>Moderator: Derek Duncan, LIGHTHOUSE Instruments</i></p> <p>Best practices for addressing container closure integrity (CCI) have evolved in recent years. Please join this session to get insight into evolving regulatory expectations for CCI and ways the industry is responding to the changing CCI landscape.</p> |
| | <p>Choosing the Right Container for mRNA drugs <i>SCHOTT</i></p> | <p>Updates on the Container Closure Guideline <i>U.S. FDA</i></p> |
| | <p>The Necessity of Extractable & Leachable Qualifications for Lyophilized Drug Products: Some Misconceptions Addressed <i>Nelson Labs</i></p> | <p>Use of X-Ray Computerized Tomography to Study Porosity, Roughness, and Contact Problems in Medical Container's Elastomeric Components <i>BD</i></p> |
| | <p>Extended Drug Stability for High pH – Superior Leachables Results for Dissolved Glass Elements <i>SCHOTT</i></p> | <p>Challenges in Container Closure Development <i>Eli Lilly & Company</i></p> |
| | <p>Q&A, Discussion <i>Moderator: Robert Ovadia, Gilead</i></p> | <p>Q&A, Discussion <i>Moderator: Derek Duncan, LIGHTHOUSE Instruments</i></p> |

12:45 LUNCH BREAK, POSTER SESSION & EXHIBITION

CLOSING PLENARY: Stepping into a More Sustainable and Patient-Centric Future

Moderator: **Bettine Boltres, WEST**

The last session will be all about our future! How can we all contribute to making the pharma industry more environmentally sustainable? And what is the way to develop a patient-centric product in the future? Let's all dive into an exchange on how to create a better future for everyone!

Net Zero Drug Delivery Devices - A Pharma Supply Chain Collaboration

Ypsomed & SCHOTT on behalf of Alliance to Zero

Re-Inventing for a more Sustainable Healthcare with Designed for Recycling Circular Raw Materials

Borealis

14:35 Coffee Break, Poster Session & Exhibition

Patient-centric Development through Product Differentiation of Biopharmaceutical Drug Products

Ten23 Health

Closing Panel Discussion

Moderator:
Bettine Boltres, WEST

Conference Summaries by the Chairs

Roman Mathaes, *LONZA*
Bettine Boltres, *WEST*

Closing Remarks & Farewell

Falk Klar, PDA

16:30 END OF CONFERENCE

Agenda is subject to change without notice, all speakers are invited and pending confirmation

VENUE

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SPECIAL REQUIREMENTS

 If you require special assistance to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to info@pda.org.

PDA EUROPE UPCOMING CONFERENCES AND EVENTS



FOR FURTHER INFORMATION
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2022

28. Feb 2022

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|----------------|--|----------------------------|
| 26-27 APR 2022 | 2022 PDA Visual Inspection Forum | Berlin, Germany |
| 16-17 MAY 2022 | 2022 PDA Medical Devices and Connected Health Conference | Dublin, Ireland |
| 16-17 MAY 2022 | 2022 PDA Robotics and Automation Conference | Dublin, Ireland |
| 18-19 MAY 2022 | 2022 PDA Annex 1 Workshop | Dublin, Ireland |
| 02-03 JUN 2022 | 2022 PDA Parenteral Packaging Conference | Basel, Switzerland |
| 20-21 JUN 2022 | 2022 PDA Virus Conference | Brussels, Belgium |
| 22-23 JUN 2022 | 2022 PDA Advanced Therapy Medicinal Products Conference | Brussels, Belgium |
| 20-21 SEP 2022 | 2022 PDA BioManufacturing Conference | Amsterdam, The Netherlands |
| 22-23 SEP 2022 | 2022 PDA Annex 1 Workshop | Amsterdam, The Netherlands |
| 05-06 OCT 2022 | 2022 PDA Quality and Regulations Conference | Amsterdam, The Netherlands |