Agenda

PDA Parenteral Packaging Conference 2025

Tuesday, 25 March

09:00 – 09:05

Welcome and Introduction

Committee Member: Falk Klar, **PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*

09:05 – 09:15

Welcome from the Co-Chairs

Co-Chair: Coralie A. Richard, **PhD**, Director, *Eli Lilly and Company*

Co-Chair: Philippe Lauwers, Technology Development Director, *Terumo Pharmaceutical Solutions*

09:15 – 10:25

Opening Plenary Part I

This session will explore how thoughtful packaging design can enhance usability for healthcare providers and improve patient outcomes in hospital settings. Updates on the new Umbrella Guidance for Container Closure Systems will be presented, outlining its implications for regulatory compliance and drug safety. Additionally, cutting-edge research on silicone oil coatings will reveal their impact on protein aggregation and biopharmaceutical packaging performance.

Moderator: Philippe Lauwers, Technology Development Director, *Terumo Pharmaceutical Solutions*

09:15 – 09:40

Optimizing Drug Packaging for Healthcare Providers: Bridging Design, Usability, and Patient Impact in Hospitals

Keynote Speaker: Prit Patel, **PharmD, BCSCP**, Pharmacy Supply Chain Supervisor, *Atrium Health*

09:40 – 10:00

Title To Be Announced

Presenter: Penney Cowan

10:00 – 10:25

Evaluating Silicone Oil Coatings: From Layer Mobility to Protein Aggregation in Biopharmaceutical Packaging

Academic Presenter: Daniel Fuchs, **Pharmacist**, PhD student, *Ludwig-Maximilians-Universität München*

10:25 – 11:05

Guided Poster Walk Part I

Moderator: Miho Soma, Sr. Engineer, *Gilead Sciences, Inc*

Agenda

PDA Parenteral Packaging Conference 2025

10:35 – 11:05

Networking Coffee Break & Exhibition

11:05 – 12:35

Opening Plenary Part II

Moderator: Philippe Lauwers, Technology Development Director, *Terumo Pharmaceutical Solutions*

11:25 – 11:45

New Umbrella Guidance on Container Closure Systems for Drugs, Including Biological Products that Replaced the 1999 Guidance

Regulatory Presenter: Madushini N. Dharmasena, **PhD**, Senior Pharmaceutical Quality Assessor, OPQ, CDER, *U.S. FDA*

11:45 – 11:55

Interactive Questionnaire Session

Moderator: Philippe Lauwers, Technology Development Director, *Terumo Pharmaceutical Solutions*

11:55 – 12:35

Plenary Discussion

Moderator: Philippe Lauwers, Technology Development Director, *Terumo Pharmaceutical Solutions*

Panelist: Penney Cowan

Regulatory Panelist: Madushini N. Dharmasena, **PhD**, Senior Pharmaceutical Quality Assessor, OPQ, CDER, *U.S. FDA*

Academic Panelist: Daniel Fuchs, **Pharmacist**, PhD student, *Ludwig-Maximilians-Universität München*

Regulatory Panelist: Claudia Müller

Panelist: Prit Patel, **PharmD, BCSCP**, Pharmacy Supply Chain Supervisor, *Atrium Health*

12:35 – 13:50

Networking Lunch Break, Exhibition & Tech Talks

13:50 – 15:10

Session 1 Track A: Container Closure Integrity Testing

Container Closure Integrity Testing (CCIT) is a test to check if a container is properly sealed and prevents leaks. The container's closure system should maintain a sterile barrier against contamination, ensuring the safety and stability of a drug product throughout its shelf life by preventing external factors like air, moisture, and microorganisms from entering the primary package. This session will discuss Glass Containers used for Cryogenic Storage Solutions, CCIT method development, validation, and controls used.

Moderator: Madushini N. Dharmasena, **PhD**, Senior Pharmaceutical Quality Assessor, OPQ, CDER, *U.S. FDA*

13:50 – 14:05

Cryogenic Storage Solutions in Glass Containers

Presenter: Adam Sarafian, **PhD**, Research Associate, *Corning*

14:05 – 14:20

Sample Controls for CCIT Method Development and Validation

Presenter: Francesca Caprioli, **PhD**, Laboratory Director, *Lighthouse Instruments*

14:20 – 14:35

Fit-for-Purpose Container Closure Integrity Method Development for the Container Closure

Presenter: Liang Fang, **PhD**, Associated Director, Primary Packaging, *GSK*

14:35 – 15:10

Q&A Discussion

Moderator: Madushini N. Dharmasena, **PhD**, Senior Pharmaceutical Quality Assessor, OPQ, CDER, *U.S. FDA*

13:50 – 15:10

Session 1 Track B: Optimizing Packaging Quality

The quality of primary packaging components is of utmost importance to protecting the safety, efficacy, and quality of drug products. This session will provide multiple perspectives on how to assess and optimize the quality of primary packaging, including process simulation tools, evaluating particulate contamination in ready-to-use components, and recently proposed revisions to compendial chapters concerning glass containers.

Moderator: Jean-Sebastien Steffen, **MS, PhD**, Group Lead Primary Packaging and Combination Products, *Lonza*

13:50 – 14:05

Distilling Primary Packaging Insights via Digital Twin Technology

Presenter: Max Dixon

14:05 – 14:20

Quality of Nested Ready-to-Use Primary Packaging Material

Presenter: Andrea Allmendinger, Chief Scientific Officer, *ten23 health*

14:20 – 14:35

Review of Proposed Revisions to USP Glass Guidance Documents 660 and 1660

Co-Presenter: Matthew Hall, **PhD**, Technical Affairs Director, *Corning Pharmaceutical Technologies*

Co-Presenter: Folker Steden, **Dr**, Senior Principal Expert, Director Product Management, *Schott Tubing*

14:35 – 15:10

Q&A Discussion

Moderator: Jean-Sebastien Steffen, **MS, PhD**, Group Lead Primary Packaging and Combination Products, *Lonza*

15:10 – 15:40

Guided Poster Walk Part II

Moderator: Philippe Lauwers, Technology Development Director, *Terumo Pharmaceutical Solutions*

15:25 – 15:55

Networking Coffee Break & Exhibition

15:55 – 17:15

Session 2 Track A: Sustainability in Pharma Packaging

Session Description: I think sustainability is here to stay! So, it is not whether or not we need to do something, it is about what we can do and how we can do it. So, this session provides some very useful insights into how you can integrate sustainability into your daily business routine and ensure that your company reaches its set sustainability goals! Be inspired by the success of others.

Moderator: Bettine Boltres, **PhD**, Director Scientific Affairs & Technical Solutions, Integrated Systems, *West Pharmaceutical Services*

15:55 – 16:10

Navigating Today's Challenges and Tomorrow's Innovations in Medical and Pharmaceutical Disposal

Academic Presenter: Srividya Narayanan, **MDS MSc**, Student , *Northeastern University*

16:10 – 16:25

Enhancing Circularity in Pharmaceutical Packaging: The Case of Tubular Pharma Glass Recycling

Co-Presenter: Claus-Juergen Maier

Co-Presenter: Marius Amschler, **MEng**, Senior Product Manager Pharmaceutical Tubing, *SCHOTT AG*

16:25 – 16:40

Supplier Management of Parenteral Packaging Materials

Presenter: Marc Egen, **PhD**, Director Pharmaceutical Development , *Boehringer Ingelheim Pharma GmbH & Co KG*

16:40 – 17:15

Q&A, Discussion

Moderator: Bettine Boltres, **PhD**, Director Scientific Affairs & Technical Solutions, Integrated Systems, *West Pharmaceutical Services*

15:55 – 17:15

Session 2 Track B: Managing the PFAS Challenge

Joining this session will help to further understand why a restriction on Per- and Polyfluoroalkyl Substances (PFAS) was proposed, how it impacts the pharmaceutical world, and bring insights into some possible examples of how to select alternative materials.

Moderator: Bram Jongen, **PhD**, VP Materials and Surface Technologies, *Datwyler*

15:55 – 16:10

Briefing on Proposed EU Ban on PFAS (Per and Poly-Fluoroalkyl) Substances

Presenter: Louise Loughran

16:10 – 16:25

Considerations for Early-Stage Testing of Chemicals for PFAS Replacement

Presenter: Dieter Hennecke, Head of Department "Ecological Chemistry", *Fraunhofer Institute for Molecular Biology and Applied Ecology IME*

16:25 – 16:40

PFAS Concerns in the Packaging of Biopharmaceutical Components

Presenter: Alexander N. Mitropoulos, **PhD**, Director, Strategic Marketing, *Merck*

16:40 – 17:15

Q&A, Discussion

Moderator: Bram Jongen, **PhD**, VP Materials and Surface Technologies, *Datwyler*

Wednesday, 26 March

08:00 – 08:45

Packaging Science Morning Session, Track A: PFAS in the Life Cycle of Drug Delivery Devices

The Packaging Science Interest Group Team will carry on the ECHA PFAS restriction proposal discussion with the aim to promote collaboration between manufacturers, suppliers and regulatory authorities to ensure safe, effective, and compliant drug production. In particular: what does the restriction mean for you as pharmaceutical, medical device and supplier companies? And what should you be doing now?

Moderator: Tony A. Perry, **Bsc Mathematics**, Regional Director of Quality, *SCHOTT Pharma*

Agenda

PDA Parenteral Packaging Conference 2025

08:00 – 08:45

Pre-Filled Syringes Morning Session, Track B: Integrated Combination Product Development: How to De-Risk Your Way to Market

Moderator: Brigitte Reutter-Haerle, Vice President Product Management & Marketing, *Vetter*

08:05 – 08:20

Key Requirements for PFS Addressing Autoinjection

Presenter: Stefano Pilati, Technical Evaluation and Product Development Coordinator, *Stevanato Group*

08:20 – 08:35

How a Flexible Autoinjector Platform Con Accepted Different PFS Variation

Presenter: Bal Johal

08:35 – 08:45

Q&A, Discussion

Moderator: Alessandro Morandotti, Drug Containment Solutions Product Development Director, *Stevanato Group*

Panelist: Frank Bamberg, MA, Associate Director of Primary Packaging and Medical Devices, *CSL Behring*

Panelist: Bal Johal

Panelist: Stefano Pilati, Technical Evaluation and Product Development Coordinator, *Stevanato Group*

09:00 – 10:20

Session 3 Track A: Innovative Solutions for Packaging Integrity

Primary packaging systems and the therapies being filled into these systems are becoming more complex. This session presents a series of innovative approaches for assuring that the pre-filled syringe and cartridge packaging system provides appropriate protection for the drug product.

Moderator: Derek I. Duncan, PhD, Director Product Lines, *LIGHTHOUSE Instruments*

09:00 – 09:10

A Novel Approach for CCIT and AVI of Fusion-Sealed Pre-Filled Syringes (PFS) with opaque suspensions

Presenter: Matthias Kahl, Head of R&D and Lab Services, *WILCO*

09:10 – 09:20

A Holistic CCI Strategy for Ready-to-Use Cartridges

Presenter: Serena Casanova, PhD, Technical Leader, *Stevanato Group*

09:20 – 09:30

Moist Heat Sterilization as a Viable Alternative to EtO for Ready-to-Fill (RTF) Containers: Insights from a Cartridges Case Study

Co-Presenter: Juergen Tuschka, Program Manager, *Gerresheimer Regensburg GmbH*

Co-Presenter: Roberta Michelini

09:30 – 09:40

Syringe-Label-Combinations: The Ying/Yang for Product Integrity

Co-Presenter: Nadine K. Lampka, **PhD**, Senior Product Manager Pharma-Security, *Schreiner MediPharm*

Co-Presenter: Christoph Zauner

09:45 – 10:20

Q&A Discussion

Moderator: Folker Steden, **Dr**, Senior Principal Expert, Director Product Management, *Schott Tubing*

09:00 – 10:20

Session 3 Track B: Modern Packaging Solutions

This is how we like it! Modern packaging solutions are provided short and snappy by industry experts. Learn more about how to increase patient safety significantly by evaluating barrier properties of packaging materials (PDA Technical Report 27), in aseptic transfers, during intravitreal injection, and by avoiding/managing particles in Ready-To-Use (RTU) devices in modern packaging solutions.

Moderator: Folker Steden, **Dr**, Senior Principal Expert, Director Product Management, *Schott Tubing*

09:00 – 09:10

Aseptic Transfer of Primary Packaging Material to Grade A: Bridging the Gap Between Supplier, Client and Health Authorities

Presenter: Elena Celi

09:10 – 09:20

A Holistic Approach for Intravitreal Injection Combining Primary Packaging and Injection Device

Presenter: Nicolas Eon, **PhD**, Senior Technology Development Manager, *Terumo Europe nv*

09:20 – 09:30

Particulate Matter in Ready-to-Use (RTU) Parenteral Packaging: Challenges, Standards, and Future Directions

Co-Presenter: Vincent Cazanave, Device Team Leader, *Roche*

Co-Presenter: Riccardo De Rosso

Agenda

PDA Parenteral Packaging Conference 2025

09:30 – 09:45

PDA Technical Report 27 Pharmaceutical Package Integrity – Why It's Time for a Revision

Presenter: Jennifer M. Roark, Sr. Manager Scientific Affairs, *West Pharmaceutical Services*

09:45 – 10:20

Q&A Discussion

Moderator: Folker Steden, **Dr**, Senior Principal Expert, Director Product Management, *Schott Tubing*

10:20 – 10:50

Networking Coffee Break & Exhibition

10:50 – 12:10

Session 4 Track A: Sterilization & Decontamination Challenges

The rise of Ready-To-use (RTU) and decentralized production models prompts diversifying sterilization and decontamination techniques. This session will focus on the impact different techniques may have on the long-term performance of rubber components

Moderator: Matthew Hall, **PhD**, Technical Affairs Director, *Corning Pharmaceutical Technologies*

10:50 – 11:15

X-Ray as an Alternative to Gamma Irradiation: Effect on Rubber Properties and Extractables

Presenter: Tine Hardeman, **PhD**, Manager Material Development, *Datwyler*

11:15 – 11:40

The Impact of Vapor Phase Hydrogen Peroxide Surface Decontamination on Elastomeric Primary Packaging Components

Presenter: Eric Kurtz, **MBA**, Manager, Technical Product Development, *West Pharmaceutical Services, Inc.*

11:40 – 12:10

Q&A Discussion

Moderator: Matthew Hall, **PhD**, Technical Affairs Director, *Corning Pharmaceutical Technologies*

10:50 – 12:10

Session 4 Track B: Advancing Cold Chain & Pharma

The seamless integration of cutting-edge technologies and innovative strategies is critical to advancing the pharmaceutical cold chain and enabling the delivery of

safe, effective, and innovative therapies. This session will explore two transformative areas shaping the future of cold chain and pharmaceutical delivery systems.

Moderator: Arne Kloke, **PhD**, Head of Service and Sustainability Management, *SCHOTT Pharma*

10:50 – 11:15

Leveraging Simulation and Operation (S&O) Data and AI for Enhanced Visibility and Risk Mitigation in Cold Chains

Presenter: Taner Chakar, Head of Product - SkyMind, *SkyCell AG*

11:15 – 11:40

Advancing Innovation and Tackling Challenges when Transitioning to Large Volume Pharmaceuticals Devices

Co-Presenter: Jeremy Hemingway, **PE**, Pharma Practice Lead, *Stress Engineering Services*

Co-Presenter: Patrick Hoopes

11:40 – 12:10

Q&A Discussion

Moderator: Arne Kloke, **PhD**, Head of Service and Sustainability Management, *SCHOTT Pharma*

12:10 – 13:25

Networking Lunch Break, Exhibition & Tech Talks

13:25 – 14:45

Closing Plenary Part I

The closing plenary session will delve into the latest updates on US Pharmacopeia, exploring the changes and their implications for our industry. Following this, the closing panel discussion will provide a platform for an interactive exchange of ideas. The conference will end with innovative round table discussions on topics such as CCIT, USP <382>, sustainability, AI, and regulatory insights, fostering collaboration and actionable takeaways.

Moderator: Coralie A. Richard, **PhD**, Director, *Eli Lilly and Company*

13:25 – 13:35

Interactive Questionnaire Session

Moderator: Coralie A. Richard, **PhD**, Director, *Eli Lilly and Company*

13:35 – 14:00

Current USP Standards Activities Related to Drug-Device Combinations, Container Closure Integrity, Extractables and Leachables, and Elastomeric Component Functionality

Regulatory Presenter: Desmond G Hunt, **PhD**, Sr. Principal Scientist, *USP*

14:00 – 14:45

Plenary Discussion

Moderator: Coralie A. Richard, **PhD**, Director, *Eli Lilly and Company*

14:45 – 15:20

Networking Coffee Break & Exhibition

15:20 – 16:20

Closing Plenary Part II

Moderator: Coralie A. Richard, **PhD**, Director, *Eli Lilly and Company*

15:25 – 16:20

Interactive Round Table Session

Moderator: Coralie A. Richard, **PhD**, Director, *Eli Lilly and Company*

16:20 – 16:30

Co-Chairs Conference Summary

Co-Chair: Coralie A. Richard, **PhD**, Director, *Eli Lilly and Company*

Co-Chair: Philippe Lauwers, Technology Development Director, *Terumo Pharmaceutical Solutions*

16:30 – 16:35

Closing Remarks & Farewell

Committee Member: Falk Klar, **PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*