

# PDA Parenteral Packaging Conference 2026

## Agenda

### Tuesday, 14 April

CEST Daylight Time (UTC +2:00)

#### Welcome and Introduction

09:00 – 09:05 **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*

#### Welcome from the Co-Chairs

09:05 – 09:15 **Co-Chair: Coralie A. Richard PhD**, Director, *Eli Lilly and Company*

**Co-Chair: Bram Jongen PhD** Senior Vice President Materials and Surface Technologies *Datwyler*

#### Opening Plenary Part I

Kick off the PDA Parenteral Packaging Conference 2026 with a forward-looking exploration of how regulatory expectations and market dynamics are reshaping primary packaging for parenteral products. Experts will unpack the latest global regulatory considerations, practical strategies for building robust specifications, and trends in parenteral packaging. This session sets the tone for a conference focused on innovation, compliance, and lifecycle excellence.

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

##### Between Radio- and Pharmaceutical Regulations: Radiopharmacy as the Nexus of QC, Release, and Patient Care

09:15 – 09:40

- **Keynote Speaker: Emanuel Joseph MSc**, PostDoc - QM, *LMU Klinikum*

##### Building Smart and Strong Specifications for Primary Packaging Materials: Practical Steps from Compliance to Lifecycle Success

09:40 – 10:00

- **Presenter: Federico Sabini MD in Biomedical Engineering**, LCM Manager - MSAT Large Molecule Drug Product Platform, *Johnson & Johnson Innovative Medicine*

##### Title To Be Announced

10:00 – 10:25

- **Presenter: Graham Lewis** , ,

10:25 – 11:00 **LIVE Guided Poster Walk -Part I-**

10:35 – 11:05 **Networking Coffee Break & Exhibition**

#### Opening Plenary Part II

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

##### Recent Developments in European Pharmaceutical Packaging Chapters

11:05 – 11:25

- **Regulatory Presenter: Eugénie Maman** , Scientific Programme Manager, *European Directorate for the Quality of Medicines & Healthcare (EDQM)*

##### Regulatory Considerations for Container Closure System for Packaging

11:25 – 11:45

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

11:05 – 12:35

11:45 – 11:55 **Interactive Questionnaire Session**

**Q&A Discussion**

- **Moderator: Coralie A. Richard PhD**, Director, *Eli Lilly and Company*
- **Regulatory Panelist: Madushini N Dharmasena PhD**, Senior Pharmaceutical Quality Assessor, OPQ, CDER, U.S. FDA
- 11:55 – 12:35 • **Regulatory Panelist: Eugénie Maman**, Scientific Programme Manager, *European Directorate for the Quality of Medicines & Healthcare (EDQM)*
- **Panelist: Graham Lewis**,
- **Panelist: Federico Sabini MD in Biomedical Engineering**, LCM Manager - MSAT Large Molecule Drug Product Platform, *Johnson & Johnson Innovative Medicine*

12:35 – 13:50

**Networking Lunch Break, Poster Session, Exhibition & Tech Talks**

**Session 1, Track A: The Science of Silicone: From Surface Coatings to Syringe Performance**

Silicone plays a critical yet complex role in parenteral packaging, affecting both container surfaces and drug delivery performance. This session presents new insights into silicone layer behaviour and coating technologies, highlighting their impact on syringe functionality, product quality, and patient safety.

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

**Investigating the Impact of Silicone Layer Properties on Intravitreal Syringe Performance: A Case Study**

13:50 – 14:15

- **Presenter: Jari Acocella MSc**, Fellow Formulation & Process Development, *ten23 health*

13:50 – 15:10

**Thermo-rheological Study of Silicone O/W Emulsions used in Surface Coating of Parenteral Containers**

14:15 – 14:40

- **Academic Presenter: Damian Renggli BSc, MSc, PhD**, Postdoctoral Researcher, *University of Delaware*

**Q&A, Discussion**

14:40 – 15:10

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

**Session 1, Track B: Optimizing Packaging Quality**

Discover innovative approaches to container closure integrity (CCI) for injectable products. Learn how a breakthrough non-destructive method enables direct testing and explore case studies revealing why no single CCIT can address all failure modes, underscoring the need for a holistic strategy.

**Moderator: Claudia Heinl PhD**, Senior Product Manager & Scientific Affairs Pharma Tubing, *SCHOTT AG*

**Direct CCI Testing of Fully Assembled Autoinjectors Using Headspace Analysis**

13:50 – 14:15

- **Presenter: Paula Bracco PhD**, R&D Lab Director (Europe), *LIGHTHOUSE Instruments*

13:50 – 15:10

**(Not) Detecting Container Closure Integrity Failures – Some Case Studies**

14:15 – 14:40

- **Presenter: Constantin Hozsa PhD**, Project Lead Formulation Development, *Siegfried AG*

**Q&A, Discussion**

14:40 – 15:10

- **Moderator: Claudia Heinl PhD**, Senior Product Manager & Scientific Affairs Pharma Tubing, *SCHOTT AG*

15:10 – 15:50 **LIVE Guided Poster Walk -Part II-**

15:20 – 15:55 **Networking Coffee Break & Exhibition**

**Session 2, Track A: Material Science Driving Drug–Container Compatibility**

Join leading experts to explore how material and packaging science principles can resolve compatibility challenges between drug products and their containers. This interactive session will provide practical insights and strategies to address common issues encountered in drug development and sterile manufacturing, helping participants improve reliability and compliance in daily operations.

**Moderator: Jean-Sébastien Steffen MS, PhD, Group Lead Packaging Development Testing, Lonza**

**Polymer Materials in the Pharmaceutical Packaging Industry in Terms of Durability as well as Chemical and Physical Resistance**

15:55 – 16:15

- **Presenter: Ralf Lach PhD, CEO, Institut für Polymerwerkstoffe e.V.**

15:55 – 17:15

**Updates on ICH Q3E Guideline for Extractables and Leachables**

16:15 – 16:30

- **Presenter: Will Parker MS, Data Analytics, Penn State University, USA**

**A Toolbox For Early Detection of Glass Delamination in Vials**

16:30 – 16:45

- **Presenter: Farrokh Sharifi , ,**

**Q&A, Discussion**

16:45 – 17:15

- **Moderator: Jean-Sébastien Steffen MS, PhD, Group Lead Packaging Development Testing, Lonza**

**Session 2, Track B: Challenges in Lyophilization and Parenteral Containers: Surface Interaction and Process Optimization**

This session explores critical advancements and insights into the challenges of lyophilization and parenteral container systems, focusing on surface interactions and process optimization. The session will bring together expert to examine the complex interplay between container surfaces and lyophilized drug products, as well as practical strategies for optimizing processes to ensure product quality and performance.

**Moderator: Vincent Cazanave , Regulatory Program Director / Device and Combination Product, Roche**

**Influence of Surface Energy and Chemistry on Glass Vial Fogging in Lyophilized Drug Products**

15:55 – 16:15

- **Academic Presenter: Oliver Germershaus PhD, Professor for Pharmaceutical Technology of Macromolecular Drugs / Chief Scientific Officer, University of Applied Sciences and Arts Northwestern Switzerland / Partiris GmbH**

15:55 – 17:15

**Updates on PDA Technical Report 27- Pharmaceutical Packaging Integrity**

16:15 – 16:30

- **Presenter: Jennifer Roark , Scientific Director, Injectables, Kindeva**

**How Lyophilized Drug Product Appearance Can Be Impacted By Filling Recipe**

16:30 – 16:45

- **Presenter: Mostafa Nakach , ,**

**Q&A, Discussion**

16:45 – 17:15

- **Moderator: Vincent Cazanave , Regulatory Program Director / Device and Combination Product, Roche**

17:15 – 22:00 **End of Conference Day 1 & Networking Event**

**Wednesday, 15 April**

**Session 3, Track A: All About Transportation**

Discover how transport shapes packaging, sterility, and patient safety. Covering packaging standardization, regulatory challenges, extreme-condition testing, and distribution best practices, this session highlights data-driven strategies, insights from industry surveys, and international standards that safeguard component integrity and product quality across the supply chain - from manufacturing to patient delivery.

**Moderator: Max Dixon MEng, PhD, Lead Applied Sciences Engineer, Crux Product Design**

09:00 – 10:20	<b>PDA Transportation Validation Benchmarking Survey</b>	
	09:00 – 09:10	• <b>Presenter: Jahanvi Miller MBA, ,</b>
	09:10 – 09:20	• <b>Presenter: Geert JAN Moens , Global Platform Leader Vial Closure Systems, Datwyler</b>
	09:20 – 09:30	• <b>Presenter: Brandon Zurawlow , ,</b>
	09:30 – 09:40	• <b>Presenter: Charlotte Utting MSc, Laboratory Supervisor, Smithers Medical Device Testing Division</b>
<b>Q&amp;A, Discussion</b>		
09:40 – 10:20 • <b>Moderator: Max Dixon MEng, PhD, Lead Applied Sciences Engineer, Crux Product Design</b>		

**Session 3, Track B: Sustainability**

Discover how our industry is reimagining sustainability - from circular design in and renewable polymers to regulatory alignment and low-carbon cement. Learn how pioneers across the industry are transforming packaging and production to meet new regulations, reduce environmental impact, and unlock practical strategies you can apply to make your own operations smarter, greener, and future-ready.

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

09:00 – 10:20	<b>Borosilicate Glass, Cement: A Second Chance</b>	
	09:00 – 09:10	• <b>Presenter: Stephen Whettingsteel PhD, CEO &amp; Managing Director, Krysteline Technologies Ltd</b>
	09:10 – 09:20	• <b>Presenter: Bruno Morchain , Innovation &amp; Scientific Affairs Manager, Aptar Pharma Injectables</b>
	09:20 – 09:30	• <b>Presenter: Elmedina Shimaj MA, Regulatory Scientific Affairs and Liaison specialist, Stevanato Group, Nuova Ompi S.r.l Unipersonale</b>
	09:30 – 09:40	• <b>Presenter: Anja Gottschalk , Application Development Engineer, Borealis GmbH</b>
<b>Q&amp;A, Discussion</b>		
09:40 – 10:20 • <b>Moderator: Bettine Boltres PhD, Director Scientific Affairs, Integrated Systems, West</b>		

## 10:20 – 10:50 Networking Coffee Break &amp; Exhibition

**Session 4, Track A: Developing Drug Delivery Systems/Advanced Techniques**

Today's innovative therapies often pose special requirements on the primary packaging and drug delivery systems to ensure product quality, stability, and patient safety. The presentations in this session give various examples of how optimized primary packaging designs can be an effective countermeasure to the risks of interactions between medical devices and pharmaceutical ingredients and illustrate the critical interplay between device design, formulation, and analytical expertise, as well as the use of predictive modeling and simulation tools.

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

**A Guide to Generating Digital Evidence on Primary Containers Mechanical Testing**

10:50 – 11:05

- **Presenter: Peter Harley MEng, PhD, FIMechE**, Head of Technology, *Crux Product Design*

**Leveraging Advanced Characterization Techniques in Drug and Device Combination Products: Enhancing Safety, Performance, and Stability**

11:05 – 11:20

- **Presenter: Guangli Hu PhD**, Principal Scientist, *Merck & Co., Inc.*

**Challenges and Solutions of Primary Packaging in the Development of Antibody Drug Conjugates**

11:20 – 11:35

- **Presenter: Bernhard Hladik PhD**, Director Business Development, *SCHOTT Pharma AG & Co. KGaA*

**Q&A, Discussion**

11:35 – 12:10

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

**Session 4, Track B: Ready-to-Use**

Increasing demands are being placed on sterilization methods and packaging systems as the pharmaceutical industry continues to develop increasingly complex drug products. This session explores critical advancements and challenges in the sterilization and validation of parenteral packaging, emphasizing innovative approaches to ensure product safety, packaging integrity, and regulatory compliance. Attendees will gain insights into cutting-edge sterilization technologies, including vaporized hydrogen peroxide under deep vacuum conditions, as an alternative to traditional methods like ethylene oxide. This approach not only meets stringent sterility assurance requirements but also safeguards the material integrity of ready-to-use (RTU) glass vials. Complementing this discussion is a deep dive into the validation challenges of a new RTU cartridge system, with a focus on seal integrity failures and sterile barrier reliability.

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

**Rethinking Sterilization: Deep Vacuum vH<sub>2</sub>O<sub>2</sub> as an Alternative to EtO for Glass RTF Vials**

10:50 – 11:05

- **Co-Presenter: Serena Carella**, Learning Campus Experience Director, *Fedegari Autoclavi SpA*
- **Co-Presenter: Holger Krenz**,

**Beyond Bracketing: A Successful Partnership Case Study on Seal Integrity in RTU Primary Packaging**

11:05 – 11:20

- **Co-Presenter: Lee Hyland**, Sr. Technical Services Engineer, *Oliver Healthcare Packaging*
- **Co-Presenter: Alessandro Girardi**, DCS Process Developer, *Stevanato Group*

**Selecting the Proper Primary Container Closure Components for Drug Products Sensitive to Hydrogen Peroxide**

11:20 – 11:35

- **Presenter: Eric Kurtz MBA**, Manager, Technical Product Management, *West Pharma*

**Q&A, Discussion**

11:35 – 12:10

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

12:10 – 13:25 **Networking Lunch Break, Poster Session, Exhibition & Tech Talks**

#### **Closing Plenary Part I**

The world never stands still, and neither do we. Let's conclude this year's conference with two compelling keynote presentations, exploring how parenteral packaging continues to innovate for the benefit of both patients and the planet.

**Moderator: Bram Jongen PhD**, Senior Vice President Materials and Surface Technologies, *Datwyler*

#### **Making Sustainable Injectables Work: Drivers and Barriers to Adoption in Hospitals**

- **Academic Presenter: Albena Bjoerck PhD**, Associate Professor / Head of Global Business Lab, *ZHAW School of Management and Law*

13:25 – 13:50

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

13:25 – 14:35

#### **Emerging Regulations Impacting Packaging Operations**

13:50 – 14:10

- **Presenter: Stephan K. Roenninger Dr.-Ing.**, Director Compliance, External Affairs, *Amgen (Europe) GmbH*

#### **Q&A, Discussion**

14:10 – 14:35

- **Moderator: Bram Jongen PhD**, Senior Vice President Materials and Surface Technologies, *Datwyler*

14:35 – 15:05 **Networking Coffee Break & Exhibition**

15:05 – 15:10 **Passport Raffle**

#### **Closing Plenary Part II**

**Moderator: Bram Jongen PhD**, Senior Vice President Materials and Surface Technologies, *Datwyler*

15:10 – 16:20

15:10 – 15:15 **Best Poster Presentation**

15:15 – 16:20 **Interactive Session**

#### **Co-Chairs Conference Summary**

16:20 – 16:30

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

**Co-Chair: Bram Jongen PhD** Senior Vice President Materials and Surface Technologies *Datwyler*

#### **Closing Remarks & Farewell**

16:30 – 16:35

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

PDA Container Closure Integrity Testing - Basic Training Course Spring Edition 2026

16 Apr - 17 Apr

PDA Extractables and Leachables Training Course Spring Edition 2026

16 Apr - 17 Apr

PDA All About Pre-Filled Syringe Systems - Basic Training Course Spring Edition 2026

16 Apr - 17 Apr