## Agenda

### 2024 PDA Parenteral Packaging Conference

**Tuesday, 23 April**

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<tr>
<th>Time</th>
<th>Session</th>
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| 09:00 – 09:05 | Welcome and Introduction  
Committee: Falk Klar PhD PDA Europe                                           |
| 09:05 – 09:15 | Welcome from the Co-Chairs  
Co-Chair: Philippe Lauwers Director Technology Development Terumo Pharmaceutical Solutions  
Co-Chair: Derek I. Duncan PhD Director Product Line LIGHHOUSE Instruments |
| 09:15 – 10:30 | Opening Plenary Part I  
Moderator: Derek I. Duncan PhD Director Product Line LIGHOUSE Instruments |
| 09:15 – 09:40 | How to Package Presents for a Patient?  
**Patient Presenter:** Paul Guijt Volunteer International Gaucher Alliance |
| 09:40 – 10:05 | Updates from USP Packaging Chapters  
**Regulatory Presenter:** Desmond Hunt |
| 10:05 – 10:30 | Looking Across Borders – Aseptic Filling in the Food Industry  
**Presenter:** Hanno Geissler |
| 10:30 – 11:15 | Coffee Break, Exhibition & Guided Poster Walk -Part I- |
| 11:15 – 12:35 | Opening Plenary Part II  
Moderator: Derek I. Duncan PhD Director Product Line LIGHOUSE Instruments |
## Agenda

### 11:15 – 11:40
**Regulatory Updates**

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

### 11:40 – 11:55
**Interactive Questionnaire Session**

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

### 11:55 – 12:35
**Q&A, Panel Discussion**

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

**Panelist:** Desmond Hunt

**Panelist:** Hanno Geissler

**Panelist:** Paul Guijt Volunteer *International Gaucher Alliance*

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

### 12:35 – 13:50
**Lunch Break, Poster Session, Exhibition & Tech Talks**

### 13:50 – 15:10
**1A: Primary Packaging Components**

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

### 13:50 – 14:05
**Basics Glass versus Polymer Pros, Cons and Different Applications**

**Presenter:** Jochen Heinz

### 14:05 – 14:20
**How Strong is That Vial Anyway? Applying Glass Fractography to the Evaluation of Novel Glass Parenteral Packaging Technologies**

**Presenter:** Brandon Aldinger PhD Senior Scientist American Glass Research

### 14:20 – 14:35
The Effects of the Rubber Component and the Selected Analytical Method on the Moisture Content of a Freeze-Dried Cake

**Presenter:** Elke Geuzens PhD Technical and Scientific Expert Datwyler

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| 14:40 – 15:10 | Q&A, Discussion                                                      | **Moderator:** Arne Kloke PhD Head of Service and Sustainability Management SCHOTT Pharma  
**Panelist:** Jochen Heinz  
**Panelist:** Brandon Aldinger PhD Senior Scientist American Glass Research  
**Panelist:** Elke Geuzens PhD Technical and Scientific Expert Datwyler |

13:50 – 15:10

1B: Container Closure Integrity Testing

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

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| 13:50 – 14:05 | Fully Leveraging Robust CCIT Techniques when Developing PFS within a Holistic Approach | **Co-Presenter:** Jean-Sebastien Steffen MS, PhD Group Lead Primary Packaging and Combination Products Lonza  
**Co-Presenter:** Federico Sabini MD in Biomedical Engineering QC Senior Specialist Primary Packaging Materials and Combination Products Lonza AG |
| 14:05 – 14:20 | Ready to Use Cartridges: Quantitative Assessment of Container Closure Integrity | **Presenter:** Serena Casanova PhD Technical Leader Stevanato Group |
| 14:20 – 14:35 | A Finite Elements Modeling-Multiscale Contact Mechanics (FEM-MCM) Simulation Approach to Predict the Sealing Performance of a Luer Lock Connector Involving a Polymer-Glass Interface | **Presenter:** Julien Singer PhD R&D Senior Engineer BD |
| 14:40 – 15:10 | Q&A, Discussion                                                      | **Moderator:** Coralie A. Richard PhD Senior Director Eli Lilly and Company  
**Panelist:** Serena Casanova PhD Technical Leader Stevanato Group  
**Panelist:** Federico Sabini MD in Biomedical Engineering QC Senior Specialist Primary Packaging Materials and Combination |
2024 PDA Parenteral Packaging Conference

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15:10 – 15:55

Coffee Break, Exhibition & Guided Poster Walk -Part II-

15:55 – 17:15

2A: Deep Cold Storage

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

15:55 – 16:20

Vials for Deep Cold Storage - Part II

Presenter: Diana Löber Global Product Manager Vials SCHOTT Pharma AG & Co. KGaA

16:20 – 16:45

Challenges and Solutions of Container Closure Integrity Syringe Testing at -180°C

Co-Presenter: Tom Van Ginneken Head of Product Management SCHOTT AG

Co-Presenter: Paula Bracco PhD Senior Study Manager Lighthouse Instruments B.V.

16:45 – 17:15

Q&A, Discussion

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

Panelist: Diana Löber Global Product Manager Vials SCHOTT Pharma AG & Co. KGaA

Panelist: Paula Bracco PhD Senior Study Manager Lighthouse Instruments B.V.

Panelist: Tom Van Ginneken Head of Product Management SCHOTT AG

15:55 – 17:15

2B: Traceability

Moderator: Sinue Gomez PhD Materials Science Technology Director Corning Incorporated

15:55 – 16:20

Towards the Batch Report of One: Connecting Traceability Across Machines and Batches
**Presenter:** Robert T. Urquhart MBA  CEO Eagas

16:20 – 16:45

Seamless Traceability from a Single Device including GMP Process Parameter Tracking up to Pallet Aggregation

  **Co-Presenter:** Georg Schick
  **Co-Presenter:** Frank Bixenmann

16:45 – 17:15

Q&A, Discussion

  **Moderator:** Sinue Gomez PhD Materials Science Technology Director Corning Incorporated
  **Panelist:** Robert T. Urquhart MBA CEO Eagas
  **Panelist:** Georg Schick
  **Panelist:** Frank Bixenmann

17:15 – 22:00

End of Conference Day 1 & Networking Event

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**Wednesday, 24 April**

08:00 – 08:45

Packaging Science Morning Session

08:00 – 08:45

Pre-Filled Syringes Morning Session

09:00 – 10:20

3A: Drug-Primary Container Interaction

  **Moderator:** Ryan Forrey

09:00 – 09:25

Discussion of the Impact of Primary Container on PS80 and Protein Oxidation

  **Presenter:** Tingting Wang PhD Senior Research Scientist Eli Lilly and Company

09:25 – 09:50
## Factors Affecting the Formation of Chemically Derived Particles in Pharmaceutical Glass Containers

**Presenter:** Luis A. González MSc Research Scientist Corning

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## 3B: Administration Routes Different from Intravenously and Subcutaneous

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

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<td>09:00 – 09:25</td>
<td>Advancing Ocular Device Delivery: Exploring Routes, Challenges, and Innovations to Meet Patient Needs</td>
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<td><strong>Presenter:</strong> Vincent Cazanave Device Team Leader Roche</td>
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<td>09:25 – 09:50</td>
<td>Case Study of a Drug Delivery Solution for Complex Intravitreal Drugs Using Pre-Filled Syringes</td>
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<td><strong>Presenter:</strong> Nicolas Eon PhD Senior Technology Development Manager Terumo Europe nv</td>
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## Coffee Break, Poster Session & Exhibition

10:20 – 10:50

## 4A: Bag Systems & Large Volume Parenterals

10:50 – 12:10
## 2024 PDA Parenteral Packaging Conference

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

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| 10:50 – 11:15 | Positive Controls in Flexible Parenteral Packaging Container Closure Integrity Testing  
**Presenter:** Guerney D.H Hunt MS  
Research Engineer 1  
*Packaging Technologies and Inspection*  

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| 11:15 – 11:40 | Nitrosamines in Flexible Packaging Materials – A Challenge for Large Volume Parenterals  
**Presenter:** Andreas Meiser Dr-Ing  
Sr. Director of Component Development  
*Fresenius Medical Care Deutschland GmbH*  

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Director Scientific Affairs & Technical Solutions, Glass Systems  
*West Pharmaceutical Services*  
**Panelist:** Guerney D.H Hunt MS  
Research Engineer 1  
*Packaging Technologies and Inspection*  
**Panelist:** Andreas Meiser Dr-Ing  
Sr. Director of Component Development  
*Fresenius Medical Care Deutschland GmbH*  

### 10:50 – 12:10

**4B: Sustainability**

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

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| 10:50 – 11:15 | Consequences From the EU Packaging Waste Directive  
**Presenter:** Lize Jaspers dr  
Sr. Packaging Engineer  
*Amgen*  

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| 11:15 – 11:40 | Blister-Free Syringe Supply – A New, Sustainable Dress Code for Pre-Filled Syringes Proving Less Packaging for More Value  
**Presenter:** Kurt Kugler PhD  
Business Development Manager  
*Schreiner MediPharm*  

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VP Materials and Surface Technologies  
*Datwyler*  
**Presenter:** Lize Jaspers dr  
Sr. Packaging Engineer  
*Amgen*  
**Panelist:** Kurt Kugler PhD  
Business Development Manager  
*Schreiner MediPharm*  

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*PDA Parenteral Packaging Conference*
12:10 – 13:25
Lunch Break, Poster Session, Exhibition & Tech Talks

13:25 – 13:40
Interactive Questionnaire Session
   Moderator: Philippe Lauwers Director Technology Development Terumo Pharmaceutical Solutions

13:40 – 14:25
Closing Plenary Part I
   Moderator: Philippe Lauwers Director Technology Development Terumo Pharmaceutical Solutions
   13:40 – 14:00
   2023 Revision of the PDA Technical Report 43
   Co-Presenter: Alicia Gallagher
   Co-Presenter: Carol Rea Flynn
   14:00 – 14:25
   Title To Be Announced

14:25 – 14:55
Coffee Break, Poster Session & Exhibition

14:55 – 15:00
Passport Raffle
   Moderator: Melanie Decker

15:00 – 16:25
Closing Plenary Part II
   Moderator: Philippe Lauwers Director Technology Development Terumo Pharmaceutical Solutions
   15:00 – 15:20
Turning Pharma Manufacturing Circular for Zero

Co-Presenter: Stine Mikkelsen
Co-Presenter: Bo Gottlieb

15:25 – 16:10

Closing Panel Discussion

Moderator: Philippe Lauwers Director Technology Development Terumo Pharmaceutical Solutions
Regulatory Panelist: Madushini N Dharmasena PhD Senior Pharmaceutical Quality Assessor, OPQ, CDER U.S. FDA
Panelist: Carol Rea Flynn
Panelist: Alicia Gallagher
Panelist: Bo Gottlieb

16:10 – 16:25

Co-Chairs Conference Summary

Co-Chair: Derek I. Duncan PhD Director Product Line LIGHHOUSE Instruments
Co-Chair: Philippe Lauwers Director Technology Development Terumo Pharmaceutical Solutions

16:25 – 16:30

Closing Remarks & Farewell

Committee: Falk Klar PhD PDA Europe