



Agenda

2024 PDA Parenteral Packaging Conference

13:00 – 18:00 | **Registration Open**

Tuesday, 23 April

08:00 – 17:30

Registration Open

The Hangar 1-3

09:00 – 09:05

Welcome and Introduction

The Hangar 4-5

Committee Member: Falk Klar PhD *Parenteral Drug Association*

09:05 – 09:15

Welcome from the Co-Chairs

The Hangar 4-5

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

Co-Chair: Derek I Duncan PhD Director Product Lines *LIGHTHOUSE Instruments*

09:15 – 10:30

Opening Plenary Part I

The Hangar 4-5

The primary packaging of parenteral drugs continues to play a critical role not only in protecting increasingly complex therapies but also in enabling easy and effective administration of the drug to the patient. This exciting opening session gives a view on parenteral packaging from the perspective of the patient as well as from another industry. In addition, pharmacopeia and regulatory updates will be presented giving critical guidance to the industry on various topics in packaging.

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

09:15 – 09:40

How to Package Presents for a Patient?

The Hangar 4-5

Patient Presenter: Paul Guijt Volunteer *International Gaucher Alliance*

09:40 – 10:05

Updates from USP Packaging Chapters

The Hangar 4-5

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

10:05 – 10:30

Looking Across Borders – Aseptic Filling in the Food Industry



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The Hangar 4-5

Presenter: Hanno Gereon Geissler Head of Technology Services *SIG*

10:30 – 11:15

Networking Coffee Break & Exhibition

The Hangar 1-3

11:15 – 12:35

Opening Plenary Part II

The Hangar 4-5

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

11:15 – 11:40

Regulatory Updates of Container Closure Systems for Drugs, Including Biological Products

The Hangar 4-5

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

11:40 – 11:55

Interactive Questionnaire Session

The Hangar 4-5

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

11:55 – 12:35

Plenary Discussion

The Hangar 4-5

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

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

Panelist: Hanno Gereon Geissler Head of Technology Services *SIG*

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

Networking Lunch Break, Poster Session & Exhibition

The Hangar 1-3



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13:20 – 13:50

Guided Poster Walk

The Hangar 1-3

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

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

13:20 – 13:50

Electron Beam Technology – Transfer Technology for Pre-Sterilized RTU Components

The Hangar 1-3

Poster Presenter: Manfred Holzer Sales Manager IRE & Product Manager Ebeam Technology *SKAN AG*

13:20 – 13:50

Industry Perspective on a Holistic Approach to Container Closure Integrity

The Hangar 1-3

Poster Presenter: Carine Huon BSC Container Closure Integrity Scientist *Sanofi*

13:20 – 13:50

Headspace Analysis versus Helium Leak Testing

The Hangar 1-3

Poster Presenter: Suzanne Kuiper PhD Application Manager *Lighthouse Instruments*

Poster Presenter: Marissa Kateva MSc Laboratory Analyst *Lighthouse Instruments*

13:20 – 13:50

Pre-filled Syringes for Deep Cold Storage

The Hangar 1-3

Poster Presenter: Philip Bortner M.Sc. Global Product Manager Syringes *Gerresheimer Regensburg GmbH*

13:20 – 13:50

On the Evolution of Stability and Quality of Bake-on PDMS Coatings upon Extended Thermal Treatments

The Hangar 1-3

Poster Presenter: Chiara Passet

13:20 – 13:50

Positive Controls - From Kirsch to Now

The Hangar 1-3

Poster Presenter: Christian Proff PhD Senior Verification Engineer *F. Hoffmann-La Roche Ltd*



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13:20 – 13:50

Determining CCI Failure Temperature and Mechanism of PFS Performance at Ultra-Low Temperatures

[The Hangar 1-3](#)

Poster Presenter: Lena Mungenast

13:20 – 13:50

Probability of Detection Study

Poster Presenter: Bram Keymolen

13:20 – 13:50

Using Finite Element Analysis to Model Stopper Raising

[The Hangar 1-3](#)

Poster Presenter: Ana Kuschel PhD Principal Scientific Affairs *West Pharmaceutical Services, Inc.*

13:20 – 13:50

The Need for High Quality in Primary Packaging

[The Hangar 1-3](#)

Poster Presenter: Ana Kuschel PhD Principal Scientific Affairs *West Pharmaceutical Services, Inc.*

13:20 – 13:50

Aseptic Transfer of RTU Containers in Light of the New Annex 1

[The Hangar 1-3](#)

Poster Presenter: Christian Vaas

13:20 – 13:50

Container Closure Integrity Test Methods - Status Quo

[The Hangar 1-3](#)

Poster Presenter: Domingo Olivares Postigo PhD Laboratory Engineer in Primary Packaging Material and Device Testing *ten23*

13:20 – 13:50

Interaction of Machine and Packaging Material

[The Hangar 1-3](#)

Poster Presenter: Klaus Ullherr Senior Product Manager *Syntegon Technology GmbH*

13:20 – 13:50

CCI Testing of Fusion Sealed Parenterals

[The Hangar 1-3](#)



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Poster Presenter: Heinz Wolf General Manager *PTI*

13:50 – 15:10

Session 1, Track A: Primary Packaging Components

The Hangar 5

Each drug development project comes with its specific application scenario. Consequently, the appropriate parenteral packaging system requires to incorporate components that align with respective manufacturing processes, storage conditions and drug administration setting. In this session, we'll tap into examples of application scenarios and discuss how they translate into requirements and testing methods for components of the packaging system.

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

13:50 – 14:05

Materials for Drug Containers: Glass versus Polymer, Basics, Pros, Cons and Different Applications

The Hangar 5

Presenter: Jochen Heinz MEng, PhD Head of New Products & Technology *Transcoject GmbH*

14:05 – 14:20

How Strong is That Vial Anyway? Applying Glass Fractography to the Evaluation of Novel Glass Parenteral Packaging Technologies

The Hangar 5

Following the astounding success of chemically strengthened smartphone screens, pharmaceutical vial manufacturers have developed several advanced glass technologies designed to reduce breakage during filling and handling. These technologies include novel glass compositions, such as aluminosilicates and fused silica, as well as vial treatments such as chemical strengthening and friction-reducing coatings. But how would a glass manufacturer optimize vial enhancement technologies? How can a pharma company assess whether or not the higher-cost vials are likely to reduce breakage on their filling line? Strength testing, in isolation, provides raw quantitative data that appear definitive, but may be misleading. It can also be unclear how strength data collected under laboratory conditions would apply to disparate filling line processes such as dehydrogenation, capping, or lyophilization. Fracture analysis is the critical component for the proper interpretation of strength testing results. In this presentation, a process for evaluating vial technologies is described for both glass manufacturing and filling line situations. For a drug manufacturer, the first step is to perform fracture analysis on current vials that have broken the filling line. To evaluate new vials, several test methods are available: strength testing (such as with an Instron apparatus), internal pressure, impact, and thermal shock. These methods produce different stress distributions and magnitudes, which must be compared to the expected loads during the item's lifetime. After testing has concluded, fracture analysis should then be performed to determine the origin locations, flaws at the origins, and breaking stresses. This comprehensive approach provides quantitative insights into vial treatments, line handling, and flaw severity that allow rational decisions to be made about the implementation of new glass 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

The Hangar 5

The effects of the rubber component and the selected analytical method on the moisture content of a freeze-dried cake o Effects of the rubber formulation on the moisture content in the freeze-dried cake o Why different moisture contents are measured using methods like Karl-Fisher and Loss-on-Drying o The effect of low moisture rubber formulations on different types of freeze-dried cakes o The use of FT-NIR (near infrared) as a non-destructive method as an alternative to Karl-Fisher

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

14:40 – 15:10



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Q&A, Discussion

The Hangar 5

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

Panelist: Jochen Heinz MEng, PhD Head of New Products & Technology *Transcoject GmbH*

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

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

13:50 – 15:10

Session 1, Track B: Container Closure Integrity Testing

The Hangar 4

Container closure integrity is paramount in the development of pharmaceutical products. It serves multiple essential purposes, including safeguarding product quality, preventing microbial contamination, complying with safety and regulatory standards, and ensuring overall product excellence. In this session, we will delve into innovative tools and real-world case studies, aiming to construct a robust, scientifically driven dataset that bolsters an effective container closure integrity control strategy.

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

13:50 – 14:05

Fully Leveraging Robust CCIT Techniques when Developing PFS within a Holistic Approach

The Hangar 4

Parenteral drug products need to maintain container closure integrity (CCI) throughout the life cycle and shelf life. Stake needle Prefilled syringes (PFSs) are a container of choice for injectable biological products as they form the basis of easy-to-use delivery systems. Components of a PFS system fulfill dual requirements: they play a static role in terms of creating a sterility barrier while having requirements at the time of use to enable safe and ergonomic delivery of the drug. This leads component suppliers to develop optimized designs and requires the drug product manufacturer to thoroughly understand and demonstrate how this system simultaneously meets both, often contradicting requirements. Building a coherent dataset during the development of new biotherapeutics enables understanding and demonstrating how the quality attributes of the components and the process parameters collectively contribute to the maintenance of CCI. With the help of a case study, we will showcase advanced CCIT techniques that enable: - thoroughly characterize the design space offered by the combination of the plunger, barrel, and the needle shield - develop and control robust plunger stopper setting processes - and finally take into account the impact on further processing, transportation, and storage conditions (e.g. assembly, air transport, and low temperature). These activities are foundational for enabling a holistic approach to CCI for biotherapeutics in PFS.

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

The Hangar 4

An appropriate liquid leakage resistance under pressure is a fundamental requirement for crimped cartridges to guarantee dose delivery accuracy. Leakage refers to the movement of a drug through a hole, crack, or porosity in/of a component from the container or container/closure system. Container Closure Integrity (CCI) is a key requisite of cartridges that must demonstrate no penetration of microbial contamination from the surroundings to the container and thus drug degradation. Leakage propensity is also an aspect of Container Closure Integrity (CCI). The most industry-wide method to assess leakage on crimped cartridges is described in ISO 21881 – Annex F, currently under revision by the ISO committee after input from Stevanato Group. This standard testing method is destructive for the sample tested and does not give a numerical indication but just a pass/fail result. This led to the need to have very large sample sizes to differentiate between different categories of crimping. Therefore, Stevanato Group believed that a new functional method with proven robustness would help characterize the product accounting for impactful material and process parameters. The scope of the method development was that it could allow a numerical result that could easily allow for statistical inference. The testing routine is worst case compared to ISO 21881 but correlates to its results. This test is called Force to Leak and



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consists of gradually increasing the force applied to the plunges in the same setup as the Leakage Test. The maximum force that the cartridge can withstand is called Force to Leak, or FTL for short. This force is an indication of the leakage propensity. This work will present a new assessment that allows to discriminate between different crimping categories and thus reduce sample sizes. Additionally, this test allows us to identify the machine settings that guarantee optimal conditions for crimping robustness, linked to maximum values of Force to Leak.

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

[The Hangar 4](#)

Luer systems, e.g. Luer-needle hub with syringe's Luer cone tip and its Luer lock Adapter, are common interfaces on medical devices. One of the key questions in this application is about the safety guarantee and dose accuracy. It is then crucial to study the sealing between these elements. In this study, we combine the use of Finite Element Analysis (FEA) and Multiscale Contact Mechanics (MCM) to analyze the connectivity and sealing performance of a glass syringe and a plastic needle Luer hub. This methodology has been applied before to the contact between glass and rubber and this is the first time that it is used for the contact between glass and plastic materials. The use of FEA allows to calculate the contact pressures and the nominal area of contact. The surface topographies of the two surfaces were measured, over a wide wavelength range (mm to nm). Subsequently, the air and liquid interfacial flow (leakage) is calculated using Persson's MCM theory which considers the roughness and elasto-plasticity of the interfacial surfaces. The theoretical predictions are compared to experimental leak measurements by the pressure decay method. Further analysis is conducted, evidencing the key features that are responsible for good sealing.

Presenter: Julien Singer PhD R&D Senior Engineer *BD*

14:40 – 15:10

Q&A, Discussion

[The Hangar 4](#)

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 Products *Lonza AG*

Panelist: Julien Singer PhD R&D Senior Engineer *BD*

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

15:10 – 15:55

Networking Coffee Break & Exhibition

[The Hangar 1-3](#)

15:55 – 17:15

Session 2, Track A: Deep Cold Storage

[The Hangar 5](#)

Recent drug technologies require ultracold temperatures during transport and storage. These storage cryogenic conditions necessitate development of container closure systems and methods that are functional at ultra-low temperature conditions. This session will discuss Vials for Deep Cold Storage and key learnings in developing and qualifying a container closure integrity test for storage conditions down to -180°C for syringes.

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



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15:55 – 16:20

Vials for Deep Cold Storage - Part II

[The Hangar 5](#)

In the first session of 2023, the focus was on data about general CCI, strength, and inner surface alteration of vials after deep freezing. Based on the continued success of advanced therapies that require storage down to -80 °C, further research has been conducted. As lipid nanoparticles are the most common delivery systems for mRNA, investigations about their adsorption behavior to different vial surfaces have been carried out. In addition, general freezing mechanisms have been assessed to better model and predict the behavior of different filling set-ups. Further, CCI under sub-optimal conditions has been analyzed.

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

[The Hangar 5](#)

Recent drug technologies require ultracold temperatures during transport and storage. For the mRNA COVID vaccines transport temperatures were seen to go as low as -100°C. Other drug therapies, such as cell- and gene therapy might need to be stored at even lower temperatures, down to -196°C. These cryogenic conditions make the necessary lifecycle management activities difficult. Transitioning from a container (vial) to an injection device (PFS) is burdened by a lack of experience with PFS functionality and CCI at these temperatures as well as the lack of available PFS options for this intended use. Past PDA presentations have shown the limitations of standard glass syringes at low temperatures, highlighting the need for an alternative PFS to glass. This joint presentation between Lighthouse Instruments and Schott Pharma will provide more insight into the syringe performance at -180°C and specifically into container closure performance. A new CCI test method was developed that helped understand the robustness of the syringe design and evaluate the impact of critical freezing parameters, such as cooling and thawing rates. Ultimately an extensive data package was generated to demonstrate syringe CCI performance 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

[The Hangar 5](#)

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

Session 2, Track B: Traceability

[The Hangar 4](#)

Patient safety is a fundamental responsibility of the pharmaceutical industry. Counterfeit drug products pose a risk to patients and the credibility of pharmaceutical companies. Traceability of drug products is key across the entire supply chain and product life cycle to protect consumers from exposure to drugs that may be counterfeit, contaminated, or in any way harmful. In this session, we will discuss strategies and platforms for tracking medical devices and medicines that ensure safe delivery to patients.

Moderator: Sinue Gomez PhD Materials Science Technology Director *Corning Incorporated*

15:55 – 16:20



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Towards the Batch Report of One: Connecting Traceability Across Machines and Batches

The Hangar 4

Modern parenteral manufacturing operations are driving the need for greater precision and visibility in each process to supplement traditional control strategies. Unique containers can provide transparency and deliver data-based decisions that reduce risk, accelerate drug delivery, and improve patient safety. Much of the focus today is on the different types of UID that are either in use or available and how they may be read in a filling or an automated inspection machine. However, the most important aspect of the use of UIDs is the product and process data that is collected as the container travels through the different stages of the manufacturing process. This presentation will draw on the input from multiple industry stakeholders to deliver a best practice guide to container traceability.

Presenter: Robert T Urquhart MBA CEO *Eagas*

16:20 – 16:45

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

The Hangar 4

Whether it's a vaccine, a heart pill, or a life-saving emergency drug, seamless tracking ensures that medicines and drugs reach the patient intact and in their full potency. For this reason, Tracking of Medical Devices involves each drug or medical product receiving its own UDI code. Via the server, the code can be tracked throughout the packaging, transportation, and storage process, allowing valuable information such as completeness, retention time, and correctness of storage to be determined and queried. At the same time, the monitored supply chain from the manufacturer to the patient helps to ensure that manipulation, attempted counterfeiting and corruption no longer stand a chance anywhere in the world. In Europe, the USA, and many parts of Asia, the clear labeling of medicines and medical products is already required by law. But it is only a matter of time before these laws will also take effect in other parts of the world. With Uhlmann Track & Trace, we bundle our many years of expertise into a reliable system. By deploying a full range of components and our groundbreaking PEXCITE software platform, we can provide you with a flexible solution that will allow you, both now and in the future to safely undertake serializing, labeling, and aggregating – all in line with your requirements. With Uhlmann, you can keep your supply chain transparent from production to the patient and ensure brand and patient protection worldwide. With clever tracking of medical devices and us at your side as pharmaceutical experts, you will be prepared for any new regulations and laws and secure your market and sector in the long term. Furthermore, the seamless tracking of medications and medical supplies offers you further advantages: whether First Product Right, fewer sources of error or reduced waste, Uhlmann Track & Trace will allow you to promote your smart and sustainable production. Secure future-proof advantages for you, now. Our interdisciplinary team is also there for you in your area.

Co-Presenter: Georg Schick Dipl.-Ing. Strategic Product Manager Track & Trace *Uhlmann Pac-Systeme GmbH & Co KG*

Co-Presenter: Frank Bixenmann Consultant Digital Solutions Consultant Digital Solutions *Uhlmann Pac-Systeme GmbH & Co. KG*

16:45 – 17:15

Q&A, Discussion

The Hangar 4

Moderator: Sinue Gomez PhD Materials Science Technology Director *Corning Incorporated*

Panelist: Robert T Urquhart MBA CEO *Eagas*

Panelist: Georg Schick Dipl.-Ing. Strategic Product Manager Track & Trace *Uhlmann Pac-Systeme GmbH & Co KG*

Panelist: Frank Bixenmann Consultant Digital Solutions Consultant Digital Solutions *Uhlmann Pac-Systeme GmbH & Co. KG*

17:15 – 22:00

End of Conference Day 1 & Networking Event

Wednesday, 24 April

07:30 – 17:00



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Registration Open

The Hangar 1-3

08:00 – 08:45

Packaging Science Morning Session - MDR Cobalt Requirement Regulations

The Hangar 5

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

08:00 – 08:10

The Impact of the MDR Cobalt Requirement Regulations

The Hangar 5

Presenter: Ana Kuschel PhD Principal Scientific Affairs *West Pharmaceutical Services, Inc.*

08:10 – 08:45

Open Discussion

The Hangar 5

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

Panelist: Maria Bauer Product Reviewer BC *TUEV SUED PRODUCT SERVICE GmbH*

08:00 – 08:45

Pre-Filled Syringes Morning Session - Meet Future Market & Regulatory Requirements for Filling & Assembly of Pre-Filled Syringes

The Hangar 4

This session will discuss the critical parameters and points in the fill/finish and AI assembly processes. Attendees will gain a much better understanding of the interaction between packaging material/device and equipment, as well as the importance of early collaboration between pharmaceutical companies and suppliers.

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

08:00 – 08:15

The Success and Challenges of Ready-to-Use Packaging Material for Fill & Finish

The Hangar 4

Presenter: Klaus Ullherr Senior Product Manager *Syntegon Technology GmbH*

08:15 – 08:30

Key Points of Attention and Lessons Learned from the PFS-Device Assembly Point of View

The Hangar 4

Presenter: Alessandro Pettenuzzo Technical Sales Manager *Stevanato Group S.p.a.*

08:30 – 08:45



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Panel Discussion, Q&A

The Hangar 4

Panelist: Klaus Ullherr Senior Product Manager *Syntegon Technology GmbH*

Panelist: Alessandro Pettenuzzo Technical Sales Manager *Stevanato Group S.p.a.*

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

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

09:00 – 10:20

Session 3, Track B: Administration Routes Different from Intravenously and Subcutaneous

The Hangar 4

Recent years have seen remarkable progress in ocular drug delivery, tackling the intricate anatomical complexities of the eye. This session explores the realm of ocular device delivery, highlighting both opportunities and challenges in innovating to fulfill unmet patient needs while optimizing therapeutic outcomes and minimizing side effects.

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

09:00 – 09:25

Advancing Ocular Device Delivery: Exploring Routes, Challenges, and Innovations to Meet Patient Needs

The Hangar 4

Presenter: Vincent Cazanave Device Team Leader *Roche*

09:25 – 09:50

Case Study of a Drug Delivery Solution for Complex Intravitreal Drugs Using Pre-Filled Syringes

The Hangar 4

Intravitreal injection serves as a method for administering medication to address disorders affecting the posterior segment of the eye. The demand for intravitreal injections is on the rise, driven by demographic shifts and the emergence of treatments for conditions that were previously untreatable. The availability of prefilled syringes for intravitreal medications offers several well-known advantages compared to traditional vials. These advantages include the potential reduction in the risk of infectious endophthalmitis, the prevention of intraocular silicone oil droplets, and improved user-friendliness. However, it's important to note that intravitreal injections involve a direct delivery into a highly sensitive area, which presents additional requirements and challenges when compared to more conventional parenteral injections, such as subcutaneous or intramuscular injections. As a result, careful considerations are essential when choosing an appropriate drug delivery system to ensure the safe and effective treatment of eye disorders. There are three primary challenges to consider when selecting a prefilled syringe for intravitreal injections: 1. Dose Accuracy: The chosen delivery system must guarantee consistent and precise dosing for injection volumes below 100 microliters. 2. Sub-Visible Particles: The primary container must comply with the requirements outlined in USP <789> to ensure the absence of sub-visible particles. 3. Terminal Sterilization: Since prefilled syringes for intravitreal injections are used in surgical settings, they must undergo thorough terminal sterilization. This process also extends to associated accessories like the Plunger Rod and Finger Grip (Flange extender). Terumo will demonstrate how these ophthalmic requirements can be effectively addressed through innovative solutions that incorporate lubrication technology, state-of-the-art micro-dosing devices, and a redesign of associated accessories.

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

09:50 – 10:20

Q&A, Discussion

The Hangar 4

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



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Panelist: Vincent Cazanave Device Team Leader *Roche*

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

09:00 – 10:20

Session 3, Track A: Drug-Primary Container Interaction

The Hangar 5

The core property of a primary container is to ideally not interfere with the valuable ingredients inside. However, life is seldom ideal. This session will explore how various factors could affect particle formation or excipient/protein degradation through unwanted drug container interactions.

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

09:00 – 09:25

Impact of Primary Container on PS80 and Protein Oxidation

The Hangar 5

Polysorbate oxidation can potentially lead to protein degradation and loss of potency, which has been a challenge for the pharmaceutical industry for decades. Even though there are many publications in this field, the impact of primary container closure systems on PS80 and protein oxidation has not been widely studied. This presentation reports recent research on the impact of primary containers on PS80 and protein oxidation. Placebo PS80 formulations were prepared and filled into different container closure systems (CCS), including different types of glass vials and polymer vials. PS80 oxidation and protein oxidation were monitored on stability under accelerated storage conditions. ICP-MS analysis and metal spiking studies were carried out to correlate the PS80 and protein oxidation rate with metals leached from primary containers. PS80 degrades via oxidation at the fastest rate in glass vials with a high coefficient of expansion (COE), followed by glass vials with a low coefficient of expansion. In contrast, polymer vials minimized the oxidation of PS80 in most formulation conditions explored. Protein oxidation follows the same trend at low concentrations while being less impacted by the primary container at high concentrations. ICP-MS analysis demonstrated that 1) 51 COE glass has more metal leachables than 33 COE glass in this study, and 2) More metal leachables correlate with faster PS80 oxidation. Metal spiking studies confirmed the hypothesis that aluminum and iron have a synergistic catalysis effect on PS80 oxidation. Primary containers of drug products play a significant role in the rate of PS80 and protein oxidation. This study revealed a new major contributor to PS80 and protein oxidation and potential mitigation strategy for biological drug products.

Presenter: Tingting Wang PhD Senior Director *Eli Lilly and Company*

09:25 – 09:50

Factors Affecting the Formation of Chemically Derived Particles in Pharmaceutical Glass Containers

The Hangar 5

Although glass has been the primary packaging material of choice for parenteral use for over 100 years, the development of new vaccines and other structurally complex biologics poses new challenges to pharmaceutical glass containers concerning drug product quality and patient safety. For instance, particulate defects originating from chemical interactions between glass containers and parenteral formulations can potentially compromise the quality attributes of the formulation and/or cause a serious risk to patients during drug administration, especially when administered intravenously. Here we will explore various factors affecting the formation of chemically derived particles in commercially available glass containers, with emphasis on subvisible particles resulting from precipitation or solubility issues in commonly used buffers, particularly phosphate. Results of accelerated screening studies at 40°C under neutral and near-neutral pH conditions will be discussed in connection with solution and glass surface chemistry.

Presenter: Luis A González MSc Research Scientist *Corning*

09:50 – 10:20

Q&A, Discussion

The Hangar 5

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



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Panelist: Tingting Wang PhD Senior Director *Eli Lilly and Company*

Panelist: Luis A González MSc Research Scientist *Corning*

10:20 – 10:50

Networking Coffee Break, Poster Session & Exhibition

The Hangar 1-3

10:50 – 12:10

Session 4, Track A: Bag Systems & Large Volume Parenterals

The Hangar 5

This session covers two open topics around large volume parenterals, i.e, infusion bags: We will explore how to properly validate positive controls for infusion bags and how to implement this in your daily routine. Also, we will take a closer look at the materials themselves and identify nitrosamine impurities coming from the material and the respective challenges being posed for the analytical evaluation.

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

10:50 – 11:15

Positive Controls in Flexible Parenteral Packaging Container Closure Integrity Testing

The Hangar 5

System validation for container closure integrity testing with IV bags is challenging due to the type of product under test. Compared with rigid container systems such as syringes and vials, IV bags include a broader range of bag materials and thicknesses. Additionally, the standard laser drilling process used to create positive controls is more difficult to validate when applied directly to the IV bag system container. Therefore, it is important for the industry to develop appropriate practices for system validation and to consider the implications of these practices on the quality risk management (QRM) strategy across all parenteral container formats. This work focuses on the use of prefabricated surface-mount defects and the use of challenge checks for system validation. The work includes the application of a prefabricated control, such as a disc with a laser-drilled hole. Further, a method is outlined to use negative control discs with no defect to ensure that the application method itself is defensible. Disc selection is carefully made to best mimic and simulate test conditions. Positive control validation investigates the various approaches to defect types and applications. Practical strategies will be presented to manage positive control performance and system verification. Due to the high variation between types of packages, this work proposes a standardized methodology for introducing IV bag positive controls which applies broadly to the parenteral packaging space. By standardizing the type of positive control, further research can evaluate and compare bag material, product type, and the probability of events such as defect clogging. A standardized approach provides more consistent results and enables the QRM strategy to evaluate all possible outcomes outside the bounds of system performance validation. Furthermore, this method provides a realistic means for positive controls to the IV bag test environment to navigate compliance with EMA's Annex 1.

Presenter: Guernsey D.H Hunt MS Research Engineer 1 *Packaging Technologies and Inspection*

11:15 – 11:40

Nitrosamines in Flexible Packaging Materials – A Challenge for Large Volume Parenterals

The Hangar 5

When nitrosamine guidelines were introduced in 2018 due to sartan impurities, they mainly focused on APIs. At that time, there was little knowledge or awareness of packaging materials. This has two implications for large-volume parenterals (LVPs). First, the high application volume of LVPs and the low allowable intake limits proposed by the guidelines lead to exceedingly low concentration limits in LVPs. These limits are a challenge for the method development since the detection and quantification of nitrosamines are required in the PPT range – published methods for nitrosamine detection usually have LOQs in the ppm or ppb range. Second, large-volume parenterals (LVPs) are typically using flexible plastic packaging materials as container closure. Due to the liquid drug presentation and the usual sterilization by moist heat, there is a high risk for drug-container interactions that might also lead to nitrosamine contamination by the packaging materials. However, no current regulations for food, toys or medical-grade packaging material set comparable low limits for nitrosamines. Knowing that nitrosamines are ubiquitous and present at higher levels in the environment, it is challenging to identify packaging materials that fulfill these unprecedented requirements. We will give examples of nitrosamine impurities in typical flexible packaging materials (e.g. PVC and non-PVC) and discuss their impact on compliance with the nitrosamine



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guidelines and LVPs drug shortage and availability.

Presenter: Andreas Meiser Dr-Ing Sr. Director of Component Development *Fresenius Medical Care Deutschland GmbH*

11:40 – 12:10

Q&A, Discussion

[The Hangar 5](#)

Moderator: Bettine Boltres PhD 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

Session 4, Track B: Sustainability

[The Hangar 4](#)

The sustainability ball is rolling, faster than ever, also in pharma packaging. We talk you through the impact of the new EU Packaging Waste Directive and shed some light on reducing packaging for Pre-filled Syringes.

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

10:50 – 11:15

Consequences From the EU Packaging Waste Directive

[The Hangar 4](#)

Presenter: Lize Jaspers PhD Environmental Sustainability Requests Mgr' *Amgen*

11:15 – 11:40

Secure Blister-Free Syringe Supply – A New, Sustainable Dress Code for Pre-Filled Syringes Providing More Value with Less Packaging

[The Hangar 4](#)

Presenter: Nadine K. Lampka PhD Senior Product Manager Pharma-Security *Schreiner Group GmbH & Co. KG*

11:40 – 12:10

Q&A, Discussion

[The Hangar 4](#)

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

Presenter: Lize Jaspers PhD Environmental Sustainability Requests Mgr' *Amgen*

Panelist: Nadine K. Lampka PhD Senior Product Manager Pharma-Security *Schreiner Group GmbH & Co. KG*

12:10 – 13:25



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Tech Talks

The Hangar 1-3

12:45 – 12:55

Gx Elite Vials: Superior quality for de-risking of fill & finish operations

The Hangar 1-3

Tech Talk Presenter: Lothar Haaf Dipl.-Ing.(FH) Senior Manager Technical Service Tubular Glass *Gerresheimer Glas GmbH*

12:55 – 13:05

How secondary packaging supports your sustainability goals

The Hangar 1-3

In this real customer case example, you can expect to learn in under 10 minutes: Sustainability: Secondary packaging supports sustainability goals while generating big savings Packaging development: Innovative, special packaging solutions and project management are implemented to meet regulatory requirements and market trends Plastic replacement: Packaging and partition made of mono material cardboard, 100% recyclable and compostable, avoids the use of fossil raw materials Grass board option: Made from renewable raw materials, grass paper is 100% recyclable and can replace up to 30% of the pulp from wood Benefits of change, plastic to paper (real customer example): Körber solution reduces board sizes, weights, volume, costs in material, logistics, and manufacturing, and reduces carbon footprint by 28%, generating EUR 1.2M savings in packaging and lots more in freight savings.

Tech Talk Presenter: Sandro Furlan

13:05 – 13:15

VIALEX™ Vials - Exceptional Inner Surface Durability

The Hangar 1-3

This presentation will highlight the benefits of Nipro's VIALEX™ vials regarding stable processing and storage of challenging drug products: o Less interactions of drugs with the inner glass surface o Lower pH shift o Reduced risk of glass delamination o Optimized lyophilization process (less fogging)

Tech Talk Presenter: Clement Condouret

12:10 – 13:25

Networking Lunch Break, Poster Session & Exhibition

The Hangar 1-3

13:25 – 13:40

Interactive Questionnaire Session

The Hangar 4-5

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

13:40 – 14:25

Closing Plenary Part I

The Hangar 4-5



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In this plenary session, presenters will provide updates on regulatory topics and on PDA Technical Report 43, as well as on industry efforts being deployed to further reduce emissions in line with the goals of the Paris Climate Agreement. The closing panel discussion will allow us to engage in an interactive exchange of thoughts on the above topics or any other topic covered in this two-day conference.

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

13:40 – 14:00

2023 Revision of the PDA Technical Report 43

[The Hangar 4-5](#)

A revision has been published of the PDA Technical Report no. 43 “Identification and Classification of Nonconformities in Moulded and Tubular Glass Containers for Pharmaceutical Manufacturing”. This document intends to provide an overview of the classification and identification of nonconformities in empty molded glass bottles and vials, and tubular glass vials, ampoules, syringes, and cartridges. Many of the images illustrating the defects have been updated. The inclusion of nonconformities in ready-to-use containers is an addition to the 2023 revision. The updates have been made following evolving standards to maintain the document’s objective to represent best practices and provide guidance for quality decision-making. Details of these revisions will be discussed during the presentation.

Co-Presenter: Alicia Gallagher Sr. Product Development Scientist *Corning Incorporated*

Co-Presenter: Carol Rea Flynn M. Eng. Director of Field Quality, Primary Packaging Glass *Gerresheimer Glass Inc.*

14:00 – 14:25

ISO 11040-Pre-filled Syringes: Update from ISO TC76/WG2

[The Hangar 4-5](#)

Presenter: Horst Koller Dipl.-Ing. CEO *HK Packaging Consulting*

14:25 – 14:55

Networking Coffee Break, Poster Session & Exhibition

[The Hangar 1-3](#)

14:55 – 15:00

Passport Raffle

[The Hangar 4-5](#)

Moderator: Melanie Decker *Parenteral Drug Association*

15:00 – 16:25

Closing Plenary Part II

[The Hangar 4-5](#)

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

15:00 – 15:20

Turning Pharma Manufacturing Circular for Zero

[The Hangar 4-5](#)

Presenter: Bo Gottlieb MA Senior Project Manager *Novo Nordisk A/S*



Agenda

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15:25 – 16:10

Plenary Discussion

The Hangar 4-5

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 M. Eng. Director of Field Quality, Primary Packaging Glass *Gerresheimer Glass Inc.*

Panelist: Alicia Gallagher Sr. Product Development Scientist *Corning Incorporated*

Panelist: Bo Gottlieb MA Senior Project Manager *Novo Nordisk A/S*

16:10 – 16:25

Co-Chairs Conference Summary

The Hangar 4-5

Co-Chair: Derek I Duncan PhD Director Product Lines *LIGHTHOUSE Instruments*

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

16:25 – 16:30

Closing Remarks & Farewell

The Hangar 4-5

Committee Member: Falk Klar PhD *Parenteral Drug Association*