13:00 – 18:00 | Registration Open

Tuesday, 23 April

08:00 – 17:30

Registration Open

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 Lines LIGHHOUSE Instruments

09:15 – 10:30

Opening Plenary Part I

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 LIGHHOUSE 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 G. Hunt PhD Sr. Principal Scientist USP

10:05 – 10:30

Looking Across Borders – Aseptic Filling in the Food Industry

Presenter: Hanno Gereon Geissler Head of Technology Services SIG
10:30 – 11:15
Networking Coffee Break & Exhibition

10:45 – 11:15
Guided Poster Walk -Part I-
Moderator: Bram Jongen PhD VP Materials and Surface Technologies Datwyler

11:15 – 12:35
Opening Plenary Part II
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
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 Lines LIGHTHOUSE Instruments

11:55 – 12:35
Q&A, Panel Discussion
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

12:35 – 13:50
Tech Talks
13:50 – 15:10

Session 1, Track A: Primary Packaging Components

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:50 – 14:05</td>
<td>Materials for Drug Containers: Glass versus Polymer, Basics, Pros, Cons and Different Applications</td>
<td>Jochen Heinz MEng, PhD Head of New Products &amp; Technology Transcoject GmbH</td>
</tr>
<tr>
<td>14:05 – 14:20</td>
<td>How Strong is That Vial Anyway? Applying Glass Fractography to the Evaluation of Novel Glass Parenteral Packaging Technologies</td>
<td>Brandon Aldinger PhD Senior Scientist American Glass Research</td>
</tr>
<tr>
<td>14:20 – 14:35</td>
<td>The Effects of the Rubber Component and the Selected Analytical Method on the Moisture Content of a Freeze-Dried Cake</td>
<td>Elke Geuzens PhD Technical and Scientific Expert Datwyler</td>
</tr>
<tr>
<td>14:40 – 15:10</td>
<td>Q&amp;A, Discussion</td>
<td>Moderator: Arne Kloke PhD Head of Service and Sustainability Management SCHOTT Pharma</td>
</tr>
<tr>
<td></td>
<td>Panelist: Jochen Heinz MEng, PhD Head of New Products &amp; Technology Transcoject GmbH</td>
<td>Panelist: Brandon Aldinger PhD Senior Scientist American Glass Research</td>
</tr>
</tbody>
</table>
Session 1, Track B: Container Closure Integrity Testing

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**

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 understand and demonstrate how the quality attribute 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

14:05 – 14:20

**Ready to Use Cartridges: Quantitative Assessment of Container Closure Integrity**

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 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**
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 calculation 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

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

15:25 – 15:55

Guided Poster Walk -Part II-

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

15:55 – 17:15

Session 2, Track A: Deep Cold Storage

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

15:55 – 16:20

Vials for Deep Cold Storage - Part II

It is crucial to reliably evaluate the effect of bulk fill-and-finish processing on cosmetic as well as strength-affecting defects. Unfortunately, it requires a high effort to perform a dedicated line trial to assess different vial features, which are of particular interest during product development. Due to this challenge, a laboratory method has been designed to generate characteristic fill-and-finish line defects on vials in a reproducible manner. This
method was possible to be developed from comprehensive knowledge of characteristic vial defects, gained from long-standing experience in container development, strength and reliability testing, fracture analyses, as well as real-life tests on customer fill-and finish lines. In this session, the method as well as first results will be presented (e.g. the performance of an outer coating).

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

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

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

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

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

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 which 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 UID’s 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 practise 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

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 your, 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

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

Registration Open

08:00 – 08:45

Packaging Science Morning Session

Moderator: Tony A. Perry, Regional Director of Quality, SCHOTT Pharma
### 2024 PDA Parenteral Packaging Conference

**Agenda**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:10 – 08:25</td>
<td>Regulatory Perspective</td>
</tr>
<tr>
<td>08:10 – 08:45</td>
<td>Open Discussion</td>
</tr>
<tr>
<td></td>
<td><strong>Moderator:</strong> Tony A. Perry <strong>Regional Director of Quality</strong> SCHOTT Pharma</td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Maria Bauer <strong>Product Reviewer BC TUEV SUED PRODUCT SERVICE GmbH</strong></td>
</tr>
</tbody>
</table>

### Pre-Filled Syringes Morning Session

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00 – 08:45</td>
<td>Meet Future Market &amp; Regulatory Requirements for Filling Pre-Filled Syringes</td>
</tr>
</tbody>
</table>

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

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**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00 – 09:25</td>
<td>Advancing Ocular Device Delivery: Exploring Routes, Challenges, and Innovations to Meet Patient Needs</td>
</tr>
<tr>
<td></td>
<td><strong>Presenter:</strong> Vincent Cazanave <strong>Device Team Leader Roche</strong></td>
</tr>
<tr>
<td>09:25 – 09:50</td>
<td>Case Study of a Drug Delivery Solution for Complex Intravitreal Drugs Using Pre-Filled Syringes</td>
</tr>
<tr>
<td></td>
<td>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...</td>
</tr>
</tbody>
</table>
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

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

09:00 – 09:25
Impact of Primary Container on PS80 and Protein Oxidation
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 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 concentration. 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
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**

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

**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**

---

10:50 – 12:10

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

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**

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 defendable. 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 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 for events such as defect clogging. A standardized approach provides more consistent results and enables the QRM strategy to clearly 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:** Guerney 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

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 is 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 in 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 guidelines and LVPs drug shortage and availability.

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

Q&A, Discussion

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

Session 4, Track B: Sustainability

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

Presenter: Lize Jaspers PhD Sr. Packaging Engineer Amgen

11:15 – 12:10

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

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

Q&A, Discussion

Moderator: Bram Jongen PhD VP Materials and Surface Technologies Datwyler

Presenter: Lize Jaspers PhD Sr. Packaging Engineer Amgen
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:10 – 13:25</td>
<td>Tech Talks</td>
</tr>
<tr>
<td>12:10 – 13:25</td>
<td>Networking Lunch Break, Poster Session &amp; Exhibition</td>
</tr>
<tr>
<td>13:25 – 13:40</td>
<td>Interactive Questionnaire Session</td>
</tr>
<tr>
<td>13:40 – 14:25</td>
<td>Closing Plenary Part I</td>
</tr>
<tr>
<td>13:40 – 14:00</td>
<td>2023 Revision of the PDA Technical Report 43</td>
</tr>
<tr>
<td></td>
<td>2023 Revision of the PDA Technical Report 43</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Co-Presenter: Alicia Gallagher Sr. Product Development Scientist Corning Incorporated</td>
</tr>
<tr>
<td></td>
<td>Co-Presenter: Carol Rea Flynn M. Eng. Director of Field Quality, Primary Packaging Glass Gerresheimer Glass Inc.</td>
</tr>
<tr>
<td>14:00 – 14:25</td>
<td>Title To Be Announced</td>
</tr>
<tr>
<td>14:25 – 14:55</td>
<td>Networking Coffee Break, Poster Session &amp; Exhibition</td>
</tr>
</tbody>
</table>
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
  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 M. Eng. Director of Field Quality, Primary Packaging Glass Gerresheimer Glass Inc.
  Panelist: Alicia Gallagher Sr. Product Development Scientist Corning Incorporated
  Panelist: Bo Gottlieb

16:10 – 16:25
Co-Chairs Conference Summary
  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
  Committee: Falk Klar PhD PDA Europe