# 2018 PDA Container Closure Performance and Integrity Conference

*Assuring Packaging Quality in Delivery Systems*

June 13-14, 2018 | Hyatt Regency Bethesda | Bethesda, MD

*As of May 31, 2018*

## Wednesday, June 13

7:00 a.m. – 5:30 p.m.
**Registration Open**

7:00 a.m. – 8:30 a.m.
**Continental Breakfast**

8:15 a.m. – 8:30 a.m.
**Welcome and Opening Remarks from Conference Co-Chair**
**Diane Paskiet,** Director, Scientific Affairs, *West Pharmaceutical Services*

8:30 a.m. – 10:00 a.m.
**P1: Assuring Packaging Quality Across the Product Lifecycle**
**Moderator: Diane Paskiet,** Director, Scientific Affairs, *West Pharmaceutical Services*

**Session Description:** A holistic strategy for drug product quality includes building in packaging and delivery system performance properties from early development through commercialization. Integration of the drug product together with the delivery device is critical to the patient experience and ensuring successful treatments. There is a wide diversity of packaging and device delivery constituents which introduce unique risk factors for performance and integrity based upon intended use. Critical attributes for packaging and delivery system quality must be established and tested to meet the requirements of the drug product throughout its lifecycle. This session will provide an overview of regulatory expectations for evaluation of different types of device constituents, and considerations for defining quality elements for lifecycle management.

8:30 a.m. – 9:00 a.m.
**Regulatory Expectations for Packaging Quality Across the Product Lifecycle: An Industry Perspective**
**Suzette M. Roan, JD,** Senior Director, Regulatory Affairs – Devices and Combination Products, *Sanofi*

9:00 a.m. – 9:30 a.m.
**Technical Considerations for Design and Quality Evaluation of Drug Delivery Devices**
**CAPT Alan M. Stevens,** Branch Chief, General Hospital Devices Branch, CDRH, *FDA*

9:30 a.m. – 10:00 a.m.
**Questions and Answers/Discussion**

9:45 a.m. – 6:30 p.m.
**Exhibit Area Open**

10:00 a.m. – 10:45 a.m.
**Refreshment Break and Poster Presentations in Exhibit Area**

**POSTER PRESENTATIONS**

*The following posters will be presented during all refreshment breaks on Wednesday and Thursday*

1. **Development of Guidance and Standards for Vial Transfer Spikes**
   **Naresh Budhavaram, PhD,** Associate Senior Consultant Engineer, *Eli Lilly and Company*
2. **Container Closure Integrity Testing of Pre-Filled Syringes**
   **Sarah Peláez, MSc**, Scientist Analytical Development*, Lonza AG*
3. **Comparing Physical Container Closure Integrity Test Methods and Artificial Leak Methodologies**
   **Sarah Peláez, MSc**, Scientist Analytical Development*, Lonza AG*
4. **Standard Test Method for Non-Destructive Detection of Leaks by Mass Extraction Method**
   **Larry Bishop**, Vice President of Engineering and Operations, *ATC*
5. **Strategy to Evaluate Container Closure Integrity at Low Temperature**
   **Matthew Gehrmann,** Senior Scientist, *West Pharmaceutical Services, Inc.*

**6. Design of a Novel Container to Prevent Cracks and Enhance Patient Safety**
**James E. Webb, PhD,** Engineering Manager, *Corning Incorporated*

10:45 a.m. – 12:15 p.m.
**P2: Implementing Qualification and Development Strategies for Inherent Package Integrity**
**Moderator: Roger Asselta,** Vice President, Technical Services, *Genesis Packaging Technologies, A Division of R-V Industries, Inc.*

**Session Description:** This session will explore examples of methodologies for assessing inherent package integrity, developing, and qualifying container closure systems.

10:45 a.m. – 11:15 a.m.
**A Case Study in the Characterization of a Container Closure to Support Sterile Product Development**
**Gary J. Mills,** Associate Director, Drug Product Development, *TESARO*

11:15 a.m. – 11:45 a.m.
**A Holistic Strategy for Optimizing an Integral Parenteral Package to Ensure Container Closure Integrity**
**Dominick DeGrazio,** Senior Associate Scientist, Drug Product Development - Large Molecules, *Janssen R&D, LLC*

11:45 a.m. – 12:15 p.m.
**Questions and Answers/Discussion**

12:15 p.m. – 1:45 p.m.
**Lunch on Your Own. Exhibit Area Closed.** *A listing of local restaurants is available at the PDA registration desk.*

1:45 p.m. – 3:15 p.m.
**P3: Integrating Quality and Regulatory Requirements in Combination Product Development**
**Moderator: Olivia Henderson,** Principal Engineer, Container Science and Engineering, *Amgen Inc.*

**Session Description:** Combination products integrate many elements of drug product development but have some different elements as well. This session will explore the different requirements and approaches to developing an integrated drug delivery device.

1:45 p.m. – 2:15 p.m.
**Build an Integrated Quality and Technical Framework to Enable Combination Product Development**
**Jon Bell,** Managing Partner/Principal, *Fulcrum PDC*

2:15 p.m. – 2:45 p.m.
**Regulatory Considerations for Drug Transfer Devices**
**Sarah Mollo,** Microbiologist, CDRH*, FDA*

2:45 p.m. – 3:15 p.m.
**Questions and Answers/Discussion**

3:15 p.m. – 4:00 p.m.
**Refreshment Break and Poster Presentations in Exhibit Area**

4:00 p.m. – 5:30 p.m.
**P4: Designing Container Closure Systems for Enhanced Functionality and Usability**
**Moderator: M. Isabel Tejero del Rio, MD, PhD,** Lead Consumer Safety Officer, CDRH, *FDA*

**Session Description:** The design of a CCS goes beyond ensuring compatibility with the drug or biologic product it will contain. It includes considerations for usability of the product by patients or clinicians, and functionality assessments to ensure that drug integrity is preserved, all parts of the CCS are compatible, and all potential risks derived from the use of different components together.

4:00 p.m. – 4:20 p.m.
**The Interface between Container Closure, Usability, and Functional Performance**
**Steven W. Badelt, PhD,** Founder and Managing Partner, *Suttons Creek, Inc.*

4:20 p.m. – 4:40 p.m.
**Microbiological Quality of Drug Products after Penetration of the Container System for Dose Preparation**
**John W. Metcalfe, PhD,** Quality Assessment Lead, Division of Microbiology Assessment, Office of Process and Facilities/Office of Pharmaceutical Quality, CDER, *FDA*

4:40 p.m. – 5:00 p.m.
**Regulatory Considerations for Complex Container Closure System**
**Carolyn Dorgan, BBME, MS,** Biomedical Engineer, CDRH, *FDA*

5:00 p.m. – 5:30 p.m.

**Questions and Answers/Discussion**

5:30 p.m. – 6:30 p.m.
**Networking Reception**

## Thursday, June 14

7:15 a.m. – 5:45 p.m.
**Registration Open**

7:15 a.m. – 8:15 a.m.
**Continental Breakfast**

7:15 a.m. – 8:15 a.m.
**Breakfast Session: Requirements and Guidelines for Performance and Integrity Testing**
**Moderator: Lei Li, PhD,** Engineering Advisor, *Eli Lilly and Company*

**Session Description:** Requirements for functionality testing in USP has been limited to testing closures intended to be pierced by a hypodermic needle for penetrability, fragmentation, and self-sealing capacity. There is now greater diversity of elastomeric components and applications, which introduces additional risk factors to consider when qualifying a component for its intended use. Appropriate performance and functionality testing is necessary for a wider range of systems needed by the end-user compared to current state of testing to a specification that may not represent actual use. This session will take a look at the proposed USP <382> chapter and application to a various container closure systems. In addition, the PDA Technical Report 27 Pharmaceutical Package Integrity, originally published in 1998, is being revised to include practical guidance on applying risk-based approach for CCI evaluation and verification throughout product lifecycle. The content will be updated to address challenges in CCI testing of novel package designs, test method selection considerations, and the emerging CCIT technologies. The session will provide an overview of the revision and highlight key current topics.

7:15 a.m. – 7:35 a.m.
**Functionality Testing for Elastomeric Closures USP Present and Future**
**Daniel L. Bantz,** Technology Manager, Product Performance and Packaging, *West Pharmaceutical Services*

7:35 a.m. – 7:55 a.m.
**A New PDA Technical Report on Package Integrity Testing: Challenges, Risk, and New Technology**
**Donald C. Singer,** Manager, Microbiology, Biopharmaceutical GMP Operations, *GlaxoSmithKline*

7:55 a.m. – 8:15 a.m.
**Question/Answer and Discussion**

8:30 a.m. – 10:00 a.m.
**P5: Container Closure Integrity Assurance throughout Manufacturing Processes**
**Moderator: Marc Hogreve,** Senior Engineer Integrity Testing Solutions, *Sartorius Stedim Biotech GmbH*

**Session Description:** Sterile drug products require the establishment of CCI of the final container. However, the maintenance of critical quality attributes, including sterility of the drug product may rely upon steps further upstream in the drug manufacturing process. CCI of specific parts of the production process may be required to maintain the drug product critical quality attributes. The use of single-use systems in these critical process steps has raised an increased regulatory scrutiny in terms of integrity assurance of various types of single-use bulk containers for liquid and frozen storage and shipping, processing, transfer, and formulation and filling. Establishing CCI of these systems in use at critical stages of the process begins with development and validation for each individual process system used in the process, and may include tests to verify CCI during the single use system lifecycle. This session focuses on assurance of CCI along the drug product manufacturing lifecycle, including principles like QRM, QbD, quality and process control, as well as integrity testing practices.

8:30 a.m. – 9:00 a.m.
**Proven Integrity: Robustness, Science, and Technologies for Proven Single-Use Container Closure Integrity**
**Carole Langlois,** Sr. Product Manager Fluid Management Technologies, *Sartorius Stedim Biotech*

9:00 a.m. – 9:30 a.m.
**Microbial Challenge Testing in an Aerosol System**
**Alexandre Mura,** Site Head, *Confarma SAS*

9:30 a.m. – 10:00 a.m.
**Questions and Answers/Discussion**

9:45 a.m. – 4:00 p.m.
**Exhibit Area Open**

10:00 a.m. – 10:45 a.m.
**Refreshment Break and Poster Presentations in Exhibit Area**

10:45 a.m. – 12:15 p.m.
**P6: Protecting the Drug Product through the Product Lifecycle: Shipping Considerations**
**Moderator: Paul Harber,** Principal, *Modality Solutions*

**Session Description:** We will look at two product categories revealing specific supply chain risks and challenges from the point of formulation to the patient bedside. Vaccines and protein solutions can be damaged when exposed to shock events. The mechanics related to this damage can be described by studying the effects of cavitation induced by filling equipment and shock events. Cellular and gene therapy products require an unbroken supply chain that must maintain very low temperatures to ensure therapeutic benefit to the patient. Measures employed in the design of the supply chain to ensure safety and efficacy will be presented.

10:45 a.m. – 11:15 a.m.
**Protein Aggregation and Particle Formation as a Function of Shock Events**
**Corinne S. Lengsfeld, PhD,** Vice Provost for Research and Graduate Education, *University of Denver*

11:15 a.m. – 11:45 a.m.
**Optimization of Capping Parameters for Maintaining Container Closure Integrity for Ultra-Low Storage Temperature**
**Pooja Sane, PhD,** Scientist, Formulation Department, *BioMarin Pharmaceutical Inc.*

11:45 a.m. – 12:15 p.m.
**Questions and Answers/Discussion**

12:15 p.m. – 1:45 p.m.
**Lunch on Your Own. Exhibit Area Closed.** *A listing of local restaurants is available at the PDA registration desk.*

1:45 p.m. – 3:15 p.m.
**P7: USP <1207> and Beyond: Novel Container Closure Integrity Testing Technologies and Applications**
**Moderator: Dominick DeGrazio,** Senior Associate Scientist, Drug Product Development - Large Molecules, *Janssen R&D, LLC*

**Session Description:** The recent USP <1207> update and the ensuing Annex 1 revision have prompted the utilization of highly sensitive and deterministic methodologies to assess container closure integrity throughout the product lifecycle. As no CCIT method is the gold standard, the need to develop novel technologies that improve leak detection, ease-of-use, and sample throughput is becoming increasingly important. Simultaneously, the use of CCIT techniques should be complemented by adequate seal quality testing. Correlating seal quality to CCIT in package development lays the foundation for a control strategy more aptly designed to mitigate CCI risk during manufacturing, release, and stability.

1:45 p.m. – 2:05 p.m.
**Optical Emission Spectroscopy, an Emerging Technology for Container Closure Integrity Testing**
**Philippe Bunod,** Product Manager - Integrity Test Solutions, *Pfeiffer Vacuum SAS*

2:05 p.m. – 2:25 p.m.
**Mechanistic Understanding of Container Closure Sealing Performance via Modeling and 4D X-Ray Computed Tomography**
**Coralie A. Richard, PhD,** Associate Senior Consultant Engineer, *Eli Lilly and Company,* and **Qingyu Zeng, PhD**, Principal Research Scientist, *West Pharmaceutical Services, Inc.*

2:25 p.m. – 2:45 p.m.
**Container Closure Integrity: Specific Strategies for Unique Applications**
**Oliver P. Stauffer,** CEO, *Packaging Technologies and Inspection*

2:45 p.m. – 3:15 p.m.
**Questions and Answers/Discussion**

3:15 p.m. – 4:00 p.m.
**Refreshment Break and Poster Presentations in Exhibit Area**

4:00 p.m. – 5:30 p.m.
**P8: Drug Product Intrinsic Interactions with Delivery Systems**
**Moderator: Lei Li, PhD,** Engineering Advisor, *Eli Lilly and Company*

**Session Description:** Drug product defines the protection requirements of its container closure system. Many new biological products, such as cellular and gene therapy products, require container closure systems maintain integrity at extremely low temperature storage conditions. Further, drug product interactions with critical components of the primary packaging system could adversely affecting integrity and performances of the container closure and drug delivery system. On the other hand, the packaging processes and delivery system design can affect how a drug product is manufactured, administrated to, and

subsequently perceived (e.g. pain) and absorbed by patient. Additional stresses may be applied to drug product during manufacturing, packaging, and dose administration; the packaging components may adulterate drug product during storage. In order to ensure patients receive high quality product at the right dose, these intrinsic interactions must be identified, characterized, and their potential impact should be taken into consideration during system design and process development.

4:00 p.m. – 4:30 p.m.
**Considerations for Container Closure Integrity Method Selection and Development - Impact of the Product, Package, and Study Goals**
**Brandon Zurawlow,** Associate Director, Container Qualification & CCIT, *Whitehouse Labs, a Division of AMRI*

4:30 p.m. – 5:00 p.m.
**Key Considerations for Assessing Impact of 100% On-Line High Voltage Leak Detection on Drug Product Stability**
**Allison L. Dill, PhD,** Sr Research Scientist, *Eli Lilly and Company*

5:00 p.m. – 5:30 p.m.
**Questions and Answers/Discussion**

5:30 p.m.
**Closing Remarks from Conference Co-Chair**
**Lei Li, PhD,** Engineering Advisor, *Eli Lilly and Company*