# 2017 PDA Container Closure, Devices and Delivery Systems: Compatibility and Material Safety Workshop

**Exploring Regulatory Expectations and Patient Considerations for the Future**

October 2-3, 2017 | Omni Shoreham Hotel | Washington, DC

Co-Sponsored by:

PQRI

As of September 19, 2017

## Monday, October 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 a.m.</td>
<td>Registration Open</td>
</tr>
<tr>
<td>7:00 a.m.</td>
<td>Continental Breakfast</td>
</tr>
<tr>
<td>8:15 a.m.</td>
<td>Welcome and Opening Remarks from Conference Co-Chair</td>
</tr>
<tr>
<td></td>
<td>Diane Paskiet, Director, Scientific Affairs, West Pharmaceutical Services</td>
</tr>
<tr>
<td>8:30 a.m.</td>
<td>P1: Opening Plenary: The Future of Drug Delivery</td>
</tr>
<tr>
<td></td>
<td>Moderator: Diane Paskiet, Director, Scientific Affairs, West Pharmaceutical Services</td>
</tr>
<tr>
<td></td>
<td><strong>Session Description:</strong> The product quality of drugs relies on the safety and compatibility of their container closure and delivery system. As the complexity of delivery systems and drug device combination products increases, the task of qualifying components fit for use becomes especially challenging. This session will give insight on how drug development is transforming the way primary packaging and delivery systems are viewed during development and throughout the product lifecycle.</td>
</tr>
<tr>
<td>9:00 a.m.</td>
<td>Considerations for Early Drug-Device Development</td>
</tr>
<tr>
<td></td>
<td>Didier Pertuy, MS, Vice President, Global Head Drug Device Integrated Development, Sanofi</td>
</tr>
<tr>
<td>9:30 a.m.</td>
<td>FDA Approach to Facilitate Development and Implementation of Emerging Pharmaceutical Technologies</td>
</tr>
<tr>
<td></td>
<td>Sau (Larry) Lee, PhD, Deputy Director, Office of Testing and Research, CDER, FDA</td>
</tr>
<tr>
<td>9:45 a.m.</td>
<td>Questions and Answers/Discussion</td>
</tr>
<tr>
<td>10:00 a.m.</td>
<td>Refreshment Break in Exhibit Area</td>
</tr>
</tbody>
</table>

---

**PQRI**

PQRI is a non-profit organization dedicated to advancing the science and practice of pharmaceutical quality research, innovation, and education. PQRI provides a platform for collaboration among industry, academia, and regulatory agencies to address critical issues in pharmaceutical quality. PQRI's mission is to improve the safety and efficacy of pharmaceuticals by fostering excellence in quality research and education.
### 10:45 a.m.-12:15 p.m.

**P2: Strategies for Safety Evaluation**

**Moderator:** Ronald G. Iacocca, PhD, Research Fellow, Device and Delivery Research & Development, *Eli Lilly and Company*

**Session Description:** Biocompatibility testing is a growing area of interest in the development and registration of combination products. This session will focus on the basic concepts of biocompatibility testing for device platforms, as well as the strategies to execute them in a meaningful way such that excessive animal testing is not required.

**Approaches to Biocompatibility Evaluation of Combination Products**

**Kathleen Lin, PhD,** Associate Senior Consultant Engineer, *Eli Lilly and Company*

**Clinical and Safety Parameters to Consider for Device-Drug/Biologic Combination Products**

**Khaudeja Bano, MD,** Senior Medical Director, *Abbott Diagnostics*

**Questions and Answers/Discussion**

12:15 p.m.-1:30 p.m.

**Networking Luncheon**

### 1:30 p.m.-3:15 p.m.

**P3: Leachables and Extractables for Combination Products that Include Both Drugs and Devices**

**Moderator:** Kim Li, PhD, DABT, MPH, Senior Manager, *Amgen Inc.*

**Session Description:** Chemical characterization is important for device-drug combination products. Risk of leachables and interaction products guides the analytical testing strategy. Extractables and leachables profiles are critical to qualifying these types of combination products, but the regulatory approaches can vary depending on the lead FDA center. There is one common purpose for leachables and extractables testing; that is to protect drug product quality and inform patient safety. This session will examine some of the different approaches to acquiring data and describes the PQRI strategy for safety thresholds and best practices.

**PQRI Strategy for Thresholds and Best Practices for Extractables and Leachables**

**Christopher T. Houston, PhD,** Director of Analytical Chemistry, *iuvo BioScience*

1:50 p.m.-2:15 p.m.

**Biocompatibility Assessment of Medical Devices**

**Jennifer L. Goode,** Biocompatibility Program Advisor, CDRH, *FDA*

2:15 p.m.-2:45 p.m.

**Chemical Characterization of Materials**

- **Considerations of Extraction for Delivery Devices**
  - **Matthew Woods,** Group Leader/Senior Chemist, *Eurofins Lancaster Laboratories*

- **Considerations of Extraction for Drug Primary Packaging**
  - **Piet Christiaens, PhD,** Scientific Director, *Toxikon Europe*

2:45 p.m.-3:15 p.m.

**Panel Discussion**

- **Christopher T. Houston, PhD,** Director of Analytical Chemistry, *iuvo BioScience*
- **Jennifer L. Goode,** Biocompatibility Program Advisor, CDRH, *FDA*
- **Piet Christiaens, PhD,** Scientific Director, *Toxikon Europe*
- **M. Isabel Tejero del Río, MD, PhD,** Lead Consumer Safety Officer, CDRH, *FDA*
- **Matthew Woods,** Group Leader/Senior Chemist, *Eurofins Lancaster Laboratories*

3:15 p.m.-4:00 p.m.

**Refreshment Break in Exhibit Area**
4:00 p.m.-5:30 p.m.  
P4: Holistic Safety & Quality Assessment  
Moderator: Ronald G. Iacocca, PhD, Research Fellow, Device and Delivery Research & Development, Eli Lilly and Company

Session Description: Safety assessment (i.e., toxicological evaluation) of leachables is a cornerstone of any pharmaceutical development program in which the issue of extractables/leachables is a concern. The session will begin with a discussion of background on the potential for safety concerns related to leachable substances, risk assessment considerations for human safety evaluation purposes, and current initiatives/proposals for safety assessment of leachables. These recommendations provided toxicologists with a process to qualify extractables in parenteral products.

4:00 p.m.-4:25 p.m.  
Current Progress in Approaches for the Safety Assessment of Extractables and Leachables  
Kim Li, PhD, DABT, MPH, Senior Manager, Amgen Inc.

4:25 p.m.-4:50 p.m.  
Review of the Extractables and Leachables Studies by the U.S. FDA: Practical Advice  
Dan Mellon, PhD, Pharmacology Toxicology Supervisor, CDER, FDA

4:50 p.m.-5:30 p.m.  
Questions and Answers/Discussion

5:30 p.m.-6:30 p.m.  
Networking Reception in Exhibit Area

Tuesday, October 3

7:00 a.m.-2:00 p.m.  
Registration Open

7:00 a.m.-8:30 a.m.  
Continental Breakfast

7:15 a.m.-8:15 a.m.  
Packaging Science Interest Group  
IG Leader: Roger Asselta, Vice President, Technical Affairs, Genesis Packaging Technologies

Session Description: This breakfast session will provide updates on current activities in the area of parenteral packaging, including Technical Reports, Tasks Forces, and regulatory Issues. It will provide an open forum for further discussion on this issue and additional topics of interest.

7:15 a.m.-7:30 a.m.  
Packaging Science Update

7:30 a.m.-8:15 a.m.  
Open Forum Discussion

8:30 a.m.-10:00 a.m.  
P5: Particle Challenges Associated with Delivery Systems and Devices  
Moderator: M. Isabel Tejero del Rio, MD, PhD, Lead Consumer Safety Officer, CDRH, FDA

Session Description: There is great a concern for contributions of particles from packaging components resulting in greater scrutiny of individual components. Understanding the sensitivity and uniqueness of particulate assessments will allow for an improved industry alignment on the subject. This session will focus current challenges associated industry initiatives for particulate evaluations and contributions from packaging components.

8:30 a.m.-9:00 a.m.  
Industry Initiatives for Visible Particulates Specifications: Pharmaceutical Manufacturers Forum  
Paolo Golfetto, Business Development Director, Ompi

9:00 a.m.-9:30 a.m.  
Impact and Consideration of Pharmaceutical Packaging on Particulates  
Fran DeGrazio, Vice President, Scientific Affairs & Technical Services, West Pharmaceutical Services

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

9:45 a.m.-1:45 p.m.  
Exhibit Area Open
10:00 a.m.-10:45 a.m.
Refreshment Break in Exhibit Area

10:45 a.m.-12:45 p.m.
P6: Compatibility of Delivery Systems with Biologics
Moderator: Nazia F. Rahman, Biomedical Engineer, CDRH, FDA

Session Description: A product formulation and its container closure must be chemically or biochemically stable to maintain the system’s integrity to be considered compatible. This session will explore correlation of biologic product quality with containment and delivery systems. This is a dynamic process that involves understanding suitability of delivery systems to preserve protein stability throughout the product lifecycle.

10:45 a.m.-11:15 a.m.
Understanding Particulates from Formulation and Container Closure: Choosing the Right Techniques to Properly Assess Particle Profiles
Amber Haynes Fradkin, PhD, Director, Particle Characterization Core Facility, KBI Biopharma

11:15 a.m.-11:45 a.m.
Qualifying Delivery System Platforms and Lifecycle Management
Susan Kirshner, PhD, Biologist, CBER, FDA

11:45 a.m.-12:15 p.m.
Product Formulation-Package Interactions: Impact on Container Closure Evaluation and Risk Mitigation Approaches for Combination Products
Lei Li, PhD, Associate Senior Consultant Engineer, Eli Lilly and Company

12:15 p.m.-12:45 p.m.
Questions and Answers/Discussion

12:45 p.m.-2:00 p.m.
Networking Luncheon

2:00 p.m.-4:00 p.m.
P7: Closing Plenary: Quality Considerations for Combination Products and Device
Moderator: Richard V. Levy, PhD, Senior Vice President, Scientific and Regulatory Affairs, PDA

Session Description: Specialty applications for drug delivery systems and devices continue to evolve and providing fit for use criteria is a challenge for suppliers. Compliance with national and international standards is a starting point but cannot encompass all uses. A set of baseline requirements can support suitability studies along with insight on quality expectations. This session will present the rationale, development, and content of the International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) baseline requirements for materials quality, discussing engagement with suppliers, lifecycle implications and relationship to risk-based concepts.

2:00 p.m. – 2:30 p.m.
A Device Perspective: Change Control for Marketed Combination Products
Kesley Gallagher, MS, Senior Regulatory Affairs Manager, Amgen Inc.

2:30 p.m. – 3:00 p.m.
Partnering across the Supply Chain to Develop and Communicate Risk-Based Requirements for Materials Quality
Lee Mia Nagao, PhD, Science Advisor, Drinker Biddle

3:00 p.m. – 3:30 p.m.
Regulatory Insight on Supplier Controls Regarding Quality of Delivery Systems
Nazia F. Rahman, Biomedical Engineer, CDRH, FDA
M. Isabel Tejero del Rio, MD, PhD, Lead Consumer Safety Officer, CDRH, FDA

3:30 p.m. – 4:00 p.m.
Questions and Answers/Discussion

4:00 p.m.
Closing Remarks from Conference Co-Chair
Ronald G. Iacocca, PhD, Research Fellow, Delivery and Device Research and Development, Eli Lilly and Company