Suitability and Compatibility for Packaging and Delivery Systems Workshop
Co-sponsored by USP and PQRI

December 9–10, 2013
USP Meetings Center
Rockville, Maryland

Preliminary Agenda
(As of December 9, 2013 – Subject to Change)

Monday, December 9, 2013 (Day 1)

7:30 a.m. **Registration & Continental Breakfast**

8:15 a.m. **USP Welcome**
Desmond G. Hunt, Ph.D., Senior Scientific Liaison, USP

Session 1: **Opening Remarks and Introduction to the Workshop**
Session Chair: Mary Foster, Pharm.D., Chair, USP General Chapters - Packaging, Storage, and Distribution Expert Committee

8:30 a.m. **Workshop Overview and Objectives:**
Mary Foster

8:40 a.m. **USP Extractables and Leachables Standards for Packaging Systems**
Michael Eakins, Ph.D., Vice-Chair, USP Packaging, Storage and Distribution Expert Committee, Eakins & Associates

9:00 a.m. **PQRI: Mission and Goals of the Extractables and Leachables Working Groups**
Reginaldo Saraceno, Ph.D. Director, Analytical Development – US Boehringer Ingelheim Pharmaceuticals, Inc. and PQRI Drug Technical Committee

9:20 a.m. **Keynote Presentation:**
The FDA's Approach to Revising the 1999 Packaging Guidance
Don Klein, Ph.D., Government Liaison, USP General Chapters - Packaging, Storage, and Distribution Expert Committee; U.S. Food and Drug Administration

9:50 a.m. **Q&A**

10:05 a.m. **Break**

Session 2: **Introduction to the USP Strategy for Establishing Suitability and Compatibility of Packaging and Delivery Systems**
Session Chair: Michael Eakins

10:20 a.m. **Compendial Standards and their Applicability**
Matthew Van Hook, J.D., Vice President and Assistant General Counsel, USP

Monday, December 9, 2013 (continued…)

10:40 a.m. **Goals and Objectives, <661> Plastic Packaging Systems and Their Materials of Construction**
Dennis Jenke, Ph.D., Member, USP General Chapters - Packaging, Storage, and Distribution Expert Committee; Baxter Healthcare Corporation

11:00 a.m. **Goals and Objectives, <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems**
Daniel Norwood, Ph.D., Member, USP General Chapters - Packaging, Storage, and Distribution Expert Committee; Boehringer-Ingelheim Pharmaceuticals Inc

11:20 a.m. **Goals and Objectives, <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems**
Lee Nagao, Ph.D., Member, USP <1664> Leachable and Best Practices Expert Panel; Drinker Biddle & Reath LLP

11:40 a.m. **Panel Discussion and Q&A**

Panel:
Matthew Van Hook, Dennis Jenke, Daniel Norwood, Lee Nagao

12:15 p.m. **Lunch**

Session 3: **<661> Plastic Packaging Systems and Their Materials of Construction**
Session Chair: Michael Ruberto, Ph.D., Member, USP General Chapters - Packaging, Storage, and Distribution Expert Committee; Material Needs Consulting

1:30 p.m. **<661.1> Plastic Materials of Construction**
Dennis Jenke

- Introduction and Scope
- Biological Reactivity
- Physiocochemical Tests
- Extractable Metals
- Plastic Additives

2:20 p.m. **<661.2> Plastic Packaging Systems for Pharmaceutical Use**
Dennis Jenke

- Introduction and Scope
- Biological Reactivity
- Physiocochemical Tests
- Safety Assessment; Extractables and Leachables
- Compatibility Assessment

2:50 p.m. **Panel Discussion and Q&A**

Panel:
Dennis Jenke, Diane Paskiet, Michael Eakins, Daniel Norwood, Michael Ruberto

3:20 p.m. **Break**

Monday, December 9, 2013 (continued…)

Session 4: **<1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems**
Session Chair: Diane Paskiet, Member, USP General Chapters - Packaging, Storage, and Distribution Expert Committee; West Pharmaceutical Services Inc.

3:40 p.m. **<1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems**
Daniel Norwood

- Introduction and Scope
- Scope
- Key Terms
- Background Information

4:10 p.m. **<1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems**
Dennis Jenke

- Generating and Characterizing Extractables
- Additional Considerations

4:30 p.m. **Panel Discussion and Q&A**

Panel:
Daniel Norwood, Cheryl Stults

5:30 p.m. **Reception and PQRI Poster Session, USP Corridor of Volunteers**

6:30 p.m. **Adjourn for the Day**

Tuesday, December 10, 2013 (Day 2)

7:45 a.m. **Registration, Continental Breakfast & PQRI Poster Session**

8:30 a.m. **Opening Remarks**
Mary Foster

Session 5: **<1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems**
Session Chair: Timothy McGovern, Ph.D., Member, USP <1664> Leachable and Best Practices Expert Panel; U.S. Food and Drug Administration

8:40 a.m. **Keynote Presentation: <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems**
Cheryl Stults, Ph.D., Member, USP <1664> Leachable and Best Practices Expert Panel; Novartis

9:15 a.m. **<1664.1> Orally Inhaled and Nasal Drug Products**
Brian Rogers, Ph.D., U.S. Food and Drug Administration

Tuesday, December 10, 2013 (continued…)

9:45 a.m. **Panel Discussion and Q&A**

Panel:
Daniel Norwood, Cheryl Stults, Lee Nagao, Brian Rogers, Ingrid Markovic

10:15 a.m. **Break**

Session 6: **Product Quality Research Institute (PQRI) Leachables and Extractables Working Group Initiatives for Parenteral and Ophthalmic Drug Product (PODP)**
Session Chair: Diane Paskiet

10:30 a.m **Program Introduction***: Diane Paskiet, West Pharmaceutical Services Inc; Chair, PQRI/PODP Leachables and Extractables Working Group*

10:35 a.m. **Application of PQRI OINDP Best Thresholds and Best Practices for Leachables and Extractables Recommendations**
Prasad Peri, Ph.D., U.S. Food and Drug Administration

11:00 a.m. **Goals and Objectives of the Parenteral and Ophthalmic Working Group**
Diane Paskiet

Session 7: **PQRI Toxicology**
Session Chair: Douglas J. Ball, Pfizer, Inc.; PQRI Toxicology Team Leader

11:15 a.m. **Utilization of the Safety Concern Threshold and the Proposed Extractable and Leachable Classification Levels for Parenteral and Ophthalmic Drug Products**
Douglas Ball

11:30 a.m. **Information and Report Formats to Facilitate Safety Qualifications**
Timothy W. Robison, Ph.D., D.A.B.T., U.S. Food and Drug Administration
Stephen A. Barat, Ph.D., Forest Laboratories

12:00 noon **Lunch**

1:00 p.m. **Risk Assessments: Toxicological Toolbox**
Jacqueline A. Kunzler, MBA, Ph.D., D.A.B.T., Baxter Healthcare

Tuesday, December 10, 2013 (continued…)

1:20 p.m. **Industry-Regulatory Panel-PODP Thresholds**
Panel Moderator: Douglas Ball

Panel:
- *Abigail Jacobs, Ph.D., U.S. Food and Drug Administration*
- *Timothy W. Robison, Ph.D., D.A.B.T., U.S. Food and Drug Administration*
- *Alisa Vespa, Health Canada*
- *Mary Richardson, Ph.D., Bausch & Lomb*
- *William P. Beierschmitt, Ph.D., Pfizer, Inc*

Session 8: PQRI Chemistry
Session Chair: Dennis Jenke, Ph.D. Baxter Healthcare; PODP Chemistry Team Leader

1:45 p.m. **Introduction of PODP Best Practices**
Dennis Jenke

2:00 p.m. **Regulatory Perspective on L/E: Quality Considerations**
Ingrid Markovic, Ph.D., U.S. Food and Drug Administration

2:30 p.m. **Break**

2:45 p.m. **Crafting Controlled Extraction and Simulation Studies for Parenteral and Ophthalmic Drug Products: Impact of Formulation on Study Design**
Christopher Houston, Ph.D., Bausch & Lomb

3:05 p.m. **Fit-for-Purpose - Analytical Concepts: Adequately Monitoring Targets while Capturing Non-Targets**
Thomas Egert, Boehringer Ingelheim Pharma GmbH & Co. KG

3:25 p.m. **Bridging the Divide: Use of Simulation Studies to Resolve the PODP Analytical Challenge**
Thomas N. Feinberg, Ph.D., Catalent Pharma Solutions

3:45 p.m. **Industry-Regulatory Panel: Putting PQRI PODP Recommendations Into Practice**
Panel Moderator: Dan Norwood

Panel:

- *Kumudini Nicholas, Health Canada*
- *Frank Holcombe, Jr., Ph.D. U.S. Food and Drug Administration; PQRI Development Technical Committee Liaison*
- *Ingrid Markovic, Ph.D., U.S. Food and Drug Administration*
- *Diane Paskiet, PQRI PODP Chair*
- *Dennis Jenke PODP Chemistry Lead*
- *Doug Ball PODP Toxicology Lead*

4:30 p.m. **Workshop Concludes**