Day 2: Suitability and Compatibility for Packaging and Delivery Systems Workshop
Co-sponsored by USP and PQRI

April 28, 2014
USP Meetings Center
Rockville, Maryland
Agenda

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**

8:40 a.m. **Keynote Presentation: <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems**
Dan Norwood, on behalf of 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

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

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 *(via Web-Ex)*
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**