Final Agenda

8:00 – 8:30 a.m. Registration & Coffee

8:30 – 8:35 a.m.
Welcome & Introduction
Catherine Sheehan, M.S., M.S., Senior Director, USP

SESSION I
General Introduction

8:35 – 8:45 a.m.
Workshop Goals and Anticipated Outcomes
Moderator: Catherine Sheehan, M.S., M.S., Senior Director, USP

8:45 – 9:45 a.m.
Introduction and Overview of Global Substance Registration System (GSRS) and Substance Registration System (SRS)
Lawrence Callahan, Ph.D., Chemist, U.S. FDA
Frank Switzer, Ph.D., Chemist, U.S. FDA

Regulatory Perspective

9:45 – 10:05 a.m. 
FDA’s Inactive Ingredient Database: How Does It Work?
Susan Zuk, MS, Branch Chief, Office of Policy for Pharmaceutical Quality, OPQ, CDER, U.S. FDA

10:05 – 10:25 a.m. 
Labeling of Inactive Ingredients
Jibril Abdus-Samad, PharmD, Policy Lead, Compendial Operations and Standards Branch/DRGS/OPPQ/OPQ/CDER, U.S. FDA

10:25 – 10:45 a.m. Q&A

10:45 – 11:00 a.m. Morning Break

Pharmacopeial Perspective

11:00 – 11:25 a.m.
USP Perspective
Excipients Nomenclature – Overview and Updates
Andrzej Wilk, Ph.D., Senior Scientific Liaison, USP
Hong Wang, Ph.D., Senior Manager, USP
What’s in a Name?
Impact of Nomenclature on Excipient Quality, Drug Product Development and Labeling Compliance

Tuesday, August 7, 2018

International Pharmacopeial Perspective

11:25 – 11:50 a.m.  ChP Perspective  
*Nomenclature of Pharmaceutical Excipients in ChP*
Xiao Ling, Ph.D., Senior Researcher and Director of Excipient Division, Institute for Food and Drug Control, Shandong Province

11:50 – 12:15 p.m.  JP Perspective  
*Excipient Nomenclature for JP*
Tamaki Miyazaki, Ph.D., Senior Researcher, Division of Drugs, National Institute of Health Sciences, Japan

12:15 – 12:30 p.m.  Q&A

SESSION II

How GSRS Naming Affects Industry  
Moderator: Katherine Ulman, Primary, KLU Consulting

Excipient Industry Perspective on Excipient Nomenclature

1:00 – 1:40 p.m.  IPEC Perspective  
Priscilla Zawislak, Chair, IPEC Americas

1:40 – 2:15 p.m.  A Generic Sponsors Perspective  
Lisa Parks, VP, Sciences and Regulatory Affairs, Association for Accessible Medicines

2:15 – 2:30 p.m.  Q&A

2:30 – 2:45 p.m.  Afternoon Break

SESSION III

Concurrent Breakout Sessions

2:45 – 3:45 p.m.  Breakout Session 1  
Moderator: Chris Moreton, Ph.D., Member, Excipient Monographs 1 Expert Committee

Case Study 1 (30 min) – Glyceryl Caprylocaprate Type I and II Confusion Regarding What Really Was Covered With the Existing NF Monograph  
David Schoneker, M.S., Director of Global Regulatory Affairs, Colorcon

Case Study (30 min) 2 – Silicone  
The Challenges in Aligning USP, SRS and IID Nomenclature of Specialized Excipients  
Katherine Ulman, Primary, KLU Consulting
2:45 – 3:45 p.m.  Breakout Session 2  
Moderator: Otilia Koo, Ph.D., Member, Excipient Monographs 1 Expert Committee

Case Study 3 (30 min) – Co-processed Excipients  
*The Challenges in Developing Nomenclature for Co-processed Excipients*  
Joseph Zeleznik, Manager, Technical & Regulatory Affairs, MEGGLE USA, Inc.

Case Study 4 (30 min) – Polysorbates  
*The Complex Composition of Polysorbate 20 and Polysorbate 80*  
Pervina Kei, Senior Research Associate, Genentech

3:45 – 4:30 p.m.  Discussion for each Case Study – Identify Key Issues and Next Steps  
- What are the challenges faced with excipient naming?  
- What do we mean by excipient grade?  
- When is grade important to excipient naming?  
- When should pharmacopeias, regulatory, and industry care about grade?  
- What is the impact of labeling and mapping of UNII's on nomenclature?

4:30 – 4:45 p.m.  Break

4:45 – 5:15 p.m.  Workshop – Summary of Key Issues of Breakouts and Next Steps

5:15 p.m.  Adjourn