

## → What's in a Name? Impact of Nomenclature on Excipient Quality, Drug Product Development and Labeling Compliance

Tuesday, August 7, 2018



### 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



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#### 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

12:30 – 1:00 p.m.

##### Lunch

#### 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

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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 UNIs 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