Draft Agenda (as of April 29 May 3, 2024)

**Event Moderator:** Duffy Mackay, USP Dietary Supplements & Herbal Medicines Stakeholder Forum Planning Committee Chair and Senior Vice President Dietary Supplements, Consumer Healthcare Products Association

8:30 a.m. – 9:00 a.m.  | Registration and Coffee and Tea Services

9:00 a.m. – 9:05 a.m.  | Welcome and Logistics  
Speaker: Jacqueline D. Starkes, Program Manager | USP

9:05 a.m. – 9:10 a.m.  | Introduction and Objectives for Today's Dietary Supplements & Herbal Medicines Stakeholder Forum  
Speaker: Duffy Mackay, | USP Dietary Supplements & Herbal Medicines Stakeholder Forum Planning Committee, Chair

9:10 a.m. – 10:10 a.m.  | USP Updates: Past, Present, and Future Activities  
**Expected Outcome:** Provide an understanding of the importance of Stakeholder Engagement for USP and an update on recent and upcoming USP activities.  
- a. Standard Development Activities Overview, Kit Goldman | USP  
- b. Monograph Compliance vs. USP Verification Program, Seong Jae Yoo | USP  
- c. Admission Evaluation for Ingredients, Nadeem Akhtar | USP

Facilitated Panel Discussion  
Moderator: Jim Griffiths, CRN, SVP International & Scientific Affairs

10:10 a.m. – 10:30 a.m.  | Chewable Gels (aka Gummies)  
**Expected Outcome:** Discuss the new insights into the manufacturing processes for gummies, their impact on quality, and the challenges associated with testing and stability.  
- a. USP Perspective, Natalia Davydova, Principal Scientist | USP  
- b. Contract Labs Perspective, Grace Bandung | Eurofins  
- c. Formulator Perspective, Ed Shneyvas, USP Non-Botanical Dietary Supplements EC, Member  
- d. Industry Perspective, Kate Banaszewski, Senior Director of Quality | NOW

Facilitated Panel Discussion  
Moderator: Mohamed Karoma, Director R&D, Pharmavite

10:30 a.m. – 10:45 a.m.  | Break

10:45 a.m. – 11:30 a.m.  | Chewable Gels (aka Gummies) (Continuation)  
**Expected Outcome:** Discuss the new insights into the manufacturing processes for gummies, their impact on quality, and the challenges associated with testing and stability.
11:30 a.m. – 12:30 p.m. Establishing Specifications for the Identification of Botanicals

**Expected Outcome:** Discuss current challenges, compendial perspectives, and any needs for identity specifications in new USP Standards.

- USP Perspective, Gabriel I. Giancaspro, Distinguished Scientific Fellow | USP
- Regulatory Perspective, Haijing Hu | U.S. FDA
- Industry Perspective, Elan Sudberg | Alkemist

**Facilitated Panel Discussion**
Moderator: Holly Johnson, Chief Science Officer | American Herbal Products Association (AHPA)

12:30 p.m. – 1:30 p.m. Lunch

1:30 p.m. – 2:30 p.m. Unique Challenges Related to Evaluating Quality of Dietary Supplements Containing Probiotics

**Expected Outcome:** Discuss the FDA’s perspectives on the USP approach to probiotic standards and share the industry is challenges in maintaining the quality of supplements containing probiotics.

- FDA’s Perspectives on Probiotics, Betsy Jean Yakes | U.S. FDA
- Methods and Challenges- Identification and Enumeration of Strains, Hanan Shehata | Purity-IQ
- Probiotic Finished Dosage Forms Quality-ID, Enumeration, Shelf Life, Overages, Marie-Eve Boyte | Probiotic Expert panel & Nutra Pharma Consulting Services

**Facilitated Panel Discussion**
Moderator: Bill Turney, Senior Director Regulatory Affairs | Kerry Foods

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:00 p.m. **Fireside Chat:** How Can We Move The Needle: Common GMP Warning Letters - Failure To Meet Specifications

**Expected Outcome:** Discuss current observations from FDA GMP inspections.

- Tyler Daniels, Senior Scientist | Thorne
- Jennifer Ahearn, CEO GMPACT
- Regulatory Perspective, Siobhan Gallager Taylor | U.S. FDA

**Facilitated Panel Discussion**
Moderator: Robert Durkin, Arnold Golden, Gregory, LLP

4:00 p.m. – 4:50 p.m. **Open Mic:** An Invitation to Bring Your Topics to The Agenda to Discuss
Moderator: Duffy MacKay, Planning Committee, Chair

4:50 p.m. – 4:58 p.m. **Next Steps/Closing Remarks/Slido Survey**
Moderator: Duffy MacKay, Planning Committee, Chair

5:00 p.m. Adjourn