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, 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, along with an update on recent and upcoming USP activities.  
Moderator: James Griffiths, Senior Vice President International & Scientific Affairs | Council for Responsible Nutrition  
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: James Griffiths, Senior Vice President International & Scientific Affairs | Council for Responsible Nutrition

10:10 a.m. – 10:20 a.m. Chewable Gels (aka Gummies)  
Expected Outcome: Discuss new insights into the manufacturing processes for gummies, their impact on quality, and the challenges associated with testing and stability.  
Moderator: Mohamed Koroma, Director R & D | Pharmavite

10:20 a.m. – 10:35 a.m. Break

10:35 a.m. – 11:30 a.m. Chewable Gels (aka Gummies) Continued  
a. Formulator Perspective: Manufacturing Processes, Ed Shneyvas, USP Non-Botanical Dietary Supplements EC | Member  
b. Industry Perspective: Impact on Quality, Katie Banaszewski, Senior Director of Quality | NOW  
c. Contract Labs Perspective: Challenges Associated with Testing, Grace Bandong | Eurofins  
d. USP Perspectives: Natalia Davydova, Principal Scientist | USP
Facilitated Panel Discussion
Moderator: Mohamed Koroma, Director R & D | Pharmavite

Establishing Specifications for the Identification of Botanicals
Expected Outcome: Discuss current challenges, compendial perspectives, and the need for identity specifications in new USP Standards.
Moderator: Holly Johnson, Chief Science Officer | American Herbal Products Association

a. USP Perspective: Robin Marles, Chair of the Botanical Dietary Supplements and Herbal Medicines EC | USP
b. Regulatory Perspective: Haijing Hu | U.S. FDA
c. Industry Perspective: Elan Sudberg | Alkemist

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

11:30 a.m. – 12:30 p.m.
Lunch

1:30 p.m. – 2:45 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's challenges in maintaining the quality of supplements containing probiotics.
Moderator: Bill Turney, Senior Director Regulatory Affairs | Kerry Foods

a. FDA's Perspectives on Probiotics: Betsy Jean Yakes | U.S. FDA
b. DNA-based Methods for Strain-Specific Identification and Enumeration of Probiotics: Hanan Shehata | Purity-IQ

c. Probiotic Finished Dosage Forms Quality: ID, Enumeration, Shelf Life, Overages, Marie-Eve Boyte | Probiotic Expert panel & Nutra Pharma Consulting Services

d. USP's Perspectives: Binu Koshy, Team Lead, Senior Scientist II | USP

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

2:45 p.m. – 3:00 p.m.
Break

3:00 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.
Moderator: Robert Durkin, Co-Chair of the Food & Drug Practice | Arnold Golden Gregory, LLP Arnold

a. Tyler Daniels, Senior Scientist | Thorne
b. Jennifer Ahearn, CEO | GMPACT

Facilitated Panel Discussion
Moderator: Robert Durkin, Co-Chair of the Food & Drug Practice | Arnold Golden Gregory, LLP
USP Stakeholder Forum

Dietary Supplements & Herbal Medicines

Wednesday, June 5, 2024 | 9:00 am - 5:00 pm EDT
Hybrid Meeting

4:00 p.m. – 4:50 p.m.  Open Mic: An Invitation to Bring Your Topics to The Agenda to Discuss
Moderator: Duffy Mackay, Dietary Supplements & Herbal Medicines Stakeholder Forum Planning Committee, Chair

4:50 p.m. – 4:58 p.m.  Next Steps/Closing Remarks/Slido Survey
Moderator: Duffy Mackay, Dietary Supplements & Herbal Medicines Stakeholder Forum Planning Committee, Chair

5:00 p.m.  Adjourn