

USP Stakeholder Forum

Dietary Supplements & Herbal Medicines



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

Hybrid Meeting

USP Rockville Headquarters | 12601 Twinbrook Parkway | Rockville, MD 20852

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.

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- 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 | Alkermis
- 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**