

USP Training Session

Taking the Guesswork out of Quality

Dietary Supplements & Herbal Medicines



Thursday, June 6, 2024 | 9:00 am - 5:00 pm EDT

Hybrid Training



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

Draft Agenda
As of May 24, 2024

Training Objective: This training is designed for individuals in quality assurance, quality control, production, and management who already have a general understanding of GMP requirements. The contents include actual case studies and direct interaction with the USP staff to facilitate your learning. This training will help you implement practical solutions within your organization to comply with GMP requirements for dietary supplements.

- 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. **USP Welcome and Opening Remarks**
Speaker: Kit Goldman, Senior Director, DSHM | USP
- 9:10 a.m. – 9:30 a.m. **Establishing appropriate specifications for dietary ingredients and dietary supplements**
Expected Outcome: Provide an understanding of setting quality specifications to help dietary supplement manufacturers comply with GMP.
Speaker: Shauna Roman, USP Non-Botanical Dietary Supplement Expert Committee
- 9:30 a.m. – 10:00 a.m. **USP Resources to Guide Dietary Supplement Testing**
Expected outcome: Provide an overview of the portfolio of standards and solutions that USP offers to help stakeholders meet the testing requirements to comply with regulations.
Speaker: Anton Bzhelyansky, Principal Scientist, DSHM | USP
- 10:00 a.m. – 10:15 a.m. **Break**
- 10:15 a.m. – 11:30 a.m. **Validating/Verifying Analytical Test Procedures- Understanding When and How to Re-validate/verify a method?**
Expected Outcome: Provide an understanding of the requirements of method validation/verification according to <1225> and <1226> and discuss its application when methods are modified.
- a. Method Development and Validation for Dietary Ingredients and Supplements, Brian May & Salika Jeelani, Senior Scientist | USP

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- b. <621> - Adjustments of Chromatographic Conditions, Edmond Biba, Senior Principal Scientist | USP
- c. Verification of Compendial Procedures, Margareth Marques, Senior Principal Scientist | USP

11:30 a.m. – 11:45 a.m. **Panel Discussion**

11:45 p.m. – 12:30 p.m. **Case Study I - Non Botanical dietary ingredients**
Expected Outcome: Gain an understanding with examples of the basis for developing specifications for Non-Botanical dietary ingredients.
Speaker: Fatkhulla K. Tadjimukhamedov, Senior Scientist I USP

12:30 p.m. – 1:30 p.m. **Networking Lunch**

1:30 p.m. – 2:00 p.m. **Case Study II - Probiotics**
Expected Outcome: Gain an understanding with examples of the basis for developing specifications for Probiotic ingredients.
Speaker: Binu Koshy, Senior Scientist I USP

2:00 p.m. – 3:15 p.m. **Case Study III - Botanical dietary ingredients**
Expected Outcome: Gain an understanding with examples of the basis for developing specifications for Botanical dietary ingredients.
Speakers: Cuiying Ma & Maria Monagas , Principal Scientist I USP

3:15 p.m. – 3:30 p.m. **Break**

3:30 p.m. – 4:15 p.m. **Case Study IV - Dietary Supplements Finished Products**
Expected Outcome: Gain an understanding with examples of the basis for developing specifications for dietary supplements.
Speaker: Natalia Davydova , Principal Scientist I USP

4:15 p.m. – 4:45 p.m. **Panel Discussion**

4:45 p.m. – 4:58 p.m. **Next Steps/Closing Remarks/Slido Survey**

5:00 p.m. **Adjourn**