USP Workshop: Hot Topics in Orally Inhaled and Nasal Drug Product Performance Testing

AGENDA

Day One: Wednesday, March 19, 2025, 8:30 a.m.

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8:30	USP Welcome and Opening Remarks Jennifer Devine, Sr. Vice President, Documentary Standards and Compendial Policy | USP

Orally Inhaled Products (OIPs): APSD Metrics and Data Interpretation
Moderators: Richard Lostritto & Anthony Hickey

8:45	1. APSD Metrics for the Quality control of OIPs – Presentation Jolyon P. Mitchell, Inhaler Consulting Services Inc. and Daryl L Roberts (Applied Particle Principles LLC)
9:15	2. FDA Perspective on APSD Metrics for the Quality control of OIPs – Presentation Nashwa El-Gendy, Senior Pharmaceutical Quality Assessor and Srinivas Behara, Senior Pharmaceutical Scientist, US FDA
10:00	3. IPAC-RS Perspective on APSD Metrics for the Quality control of OIPs – Presentation Adrian P. Goodey, Senior Principal Scientist, Analytical R&D, Merck &Co., Inc.
10:45	Morning Break

OIPs: Abbreviated Impactor Measurement (AIM) as a Complement to Development and Quality Control
Moderators: Masahiro Sakagami & Adrian Goodey

11:00	4. Abbreviated Impactor Measurement (AIM) – Presentation Jamie Clayton, Managing Director, Copley Scientific
11:45	5. Abbreviated Impactor Measurement (AIM) J. David Christopher, Executive Director, Biostatistics, Merck & Co., Inc.
12:30	Lunch Break

13:30 6. Application of Abbreviated Impactors for Inhaled Products
Jan Olof Svensson (Principal Scientist, Astra Zeneca)

14:15 7. Regulatory Perspective on Abbreviated Impactor Measurement (AIM) Topic 3
Changning Guo, Supervisory Chemist, US FDA

15:00 Afternoon Break

Compendial Considerations for the Presentation of OIP APSD Data
Moderators: Daryl Roberts, Applied Particle Principles, LLC (confirmed) & Christopher Gruenloh, Research Fellow, PPD;

15:15 8. Presentation of Cascade Impactor Data for Orally Inhaled Products (OIPs)
Jolyon P. Mitchell, Chair of the USP Inhalation Sub-committee

15:40 9. Day 1 Panel Discussion (all speakers)

16:30 Adjourn

Day Two: Thursday, March 20, 2024, 8:30 a.m.

8:30 Welcome and Day 1 Summary
Anthony Hickey, USP Inhalation Expert Sub-Committee

Current Considerations for Nasal Product Performance Tests –
Moderators: Bill Doub & Erika Stippler

8:45 10. Nasal aspects in GC <601>
Julie Suman, Vice President, Scientific Affairs, Aptar Pharma

9:00 11. Dose determination for nasal products (40 min presentation, 15 discussion)
Maria Smith, Director – Applications and Business Development, Proveris Laboratories
Julie Suman, Vice President, Scientific Affairs, Aptar Pharma

9:55 12. Method considerations to determine the mass fraction below 10 µm in nasal products (40 minutes - -- discussion)
Regina Scherliess, Professor for Pharmaceutics and Biopharmaceutics, Vice-dean Faculty of Natural Sciences at Kiel University

10:40	Morning Break
10:55	13. FDA Perspective on the Assessment of particles/droplets sized <10 microns in nasal products Xihao Li, OPQ/OPQAII/DPQAX, US FDA
11:40	14. Panel Discussion on the Assessment of particles/droplets in nasal products and gaps on USP standards Panelists: All day 2 speakers
12:10	15. Establishing and Prioritizing Unmet Needs for Attention by the Aerosols Sub-Committee of USP Dosage Forms Expert Committee During the 2025-2030 cycle All Present
12:45	Adjourn - Lunch and Networking