19th World Congress of the International Society for Aerosols in Medicine

University of North Carolina at Chapel Hill

William and Ida Friday Center for Continuing Education

ISAM One-Day Symposium

Enhancing Accordance between Outcomes of Laboratory and Clinical Testing of Orally Inhaled Drug Products

April 6, 2013

8:05 – 8:15 AM: *Opening remarks*
Gur Jai Pal Singh, AXAR Pharmaceuticals, USA

Session 1:
Current Status and Challenges
(Chair: David Cipolla)

8:15 – 8:45 AM: *OIP Performance Testing for Product Development, Registration and Quality Control of OIP*
Orest Lastow, MVIC™, Malmo, Sweden

8:45 – 9:15 AM: *Missing Links in Establishing Clinically Relevant In Vitro Performance Testing of OIP*
Gur Jai Pal Singh, AXAR Pharmaceuticals, USA

9:15 – 9:45 AM: *Enhancing Clinical Relevance of In Vitro Testing of OIP by using Appropriate In Vitro Models and Simulations*
Jolyon Mitchell, Trudell Medical Inc.

9:45 – 10:15 AM: **Coffee Break**

Session 2:

Current Regulatory Considerations
for *In Vitro* Performance Testing in Approval of OIP
(Chair: Gur Jai Pal Singh)

10:15 – 11:45 AM *In Vitro Testing in Establishment of Bioequivalence: Can we Differentiate between Device and Product*

US FDA: *FDA Perspective on OIPs: Consideration of Inhaler Devices and Possible Product Changes*
Dr. Prasad Peri, FDA, USA (20 min)

US FDA: *ANDA CMC Perspective*
Dr. Bita Mirzai-Azarm, FDA, USA (20 min)

EU: *EU Perspective on OIPs*
Alfredo Garcia-Arieta, PhD, Spanish Regulatory Agency (20 min)

Canada: *Canadian Perspective on OIPs*
Eric Ormsby, Health Canada (20 min)

11:45 – 12:30pm **Q & A: Sessions 1 & 2**

12:30 – 1:15 PM: **Lunch Break**

Session 3:

Clinical Considerations: Drug Delivery Devices and Biomarkers
(Chair: Myrna Dolovich)

1:15 – 1:45 PM *OIP Device Design: Approaches to Creating Successful Products for Patient Use*
Benjamin Cox, PhD, Team Consulting Ltd, UK

1:45 – 2:15 PM *Inhaled Product Delivery in the Hands of the Patient*
Dr. Federico Lavorini, University of Florence, Italy

2:15 – 3:15 PM *Relevant Biomarkers with Potential for Support in Regulatory Approvals for OIPs*

- Possible Biomarkers in the Determination of Clinical Efficacy of OIPs
  Dr. Param Nair, McMaster University, Canada (30 min)
- Potential Pathways for Regulatory Approval of Generic Bronchodilators: Aerosol Science and Clinical Considerations
  Dr. Gregory Geba (tentative), FDA Office of Generic Drugs (30 min)

3:15 – 3:30 PM **Coffee Break**

Session 4:
Bench to Bedside: Linking In Vitro/In Vivo
(Chair: Jolyon Mitchell)

3:30-4:00PM	*Role of Lung Imaging in Development and Regulatory Approval of OIP – Process and Issues* **Glyn Taylor, Scintigraphics, Cardiff**
4:00 - 4:30PM	*Evaluation of Comparative Performance of OIPs in View of the Classical Bioequivalence Paradigms* **S. Horhota, Boehringer Ingelheim, USA**
4:30 – 5:00PM	*OGD Perspective* **Dr. Sau Lee**, **FDA USA**
5:00 – 5:45PM	Q & A: Sessions 3 & 4
5:45 - 6:00 PM	*Closing Remarks* **A Hickey, UNC, USA**