
ISAM/IPAC-RS European Workshop on Equivalence Considerations for Orally Inhaled Products for Local Action

12-13 October 2010



Frankfurt, Germany



Introduction to the Workshop

Sue Holmes (GSK)





International Society for Aerosols in Medicine

- ISAM is an international society that aims to stimulate and further the interdisciplinary cooperation and exchange of information in all aspects of aerosol research in medicine
- <http://isam.org>



International Pharmaceutical Aerosol Consortium on Regulation and Science

- IPAC-RS is an international association of innovator and generic companies that develop, manufacture or market orally inhaled and nasal drug products (OINDPs). IPAC-RS is committed to advancing consensus-based, scientifically driven standards and regulations for these products, with the purpose of facilitating the availability of high-quality, safe, and efficacious medicines to patients.
- <http://ipacrs.com>



Organizing Committee Members

- Julianne Berry, Merck
- David Cipolla, Aradigm
- Myrna Dolovich, McMaster U
- **Carole Evans, Inspire (Co-Chair)**
- Michael Golden, Pearl
- **Sue Holmes, GSK (Co-Chair)**
- Andrea Kunze, Activaero
- Svetlana Lyapustina, DBR
- Dennis O'Connor, BI
- Ilse Peterson, DBR
- Colin Reisner, Pearl
- Dennis Sandell, s5consulting
- **Gur JP Singh, AXER (Co-Chair)**
- Terry Tougas, BI
- Pat Watson, BI



Workshop Objectives

- Stimulate constructive dialogue about equivalence considerations for OIPs between industry, regulators, academic researchers and other stakeholders
- Explore and promote best scientific and regulatory approaches to OIP equivalence determinations, especially within Europe



Day 1 Plenary Session

- **8.30 – 12.30 : Regulatory Perspectives**
 - Generic Medicines: Understanding the Legal Framework
 - EU Regulators Experience with OIP Equivalence Determinations (Netherlands, UK, Sweden, Spain)
 - Canadian Guidance: Similarity and Distinction Relative to European Approach
 - An Overview of the FDA Position and Experience

- **1.30 – 5.30 : Industry and Academic Perspectives**
 - Synopsis of the RDD/PQRI PK Workshop
 - Present and Past Approval Principals
 - Study Considerations
 - Review of the EMEA Guidelines' In-Vitro Equivalence Criteria for Cascade Impaction Data both via Simulation and Case Studies
 - Some Unresolved Issues in the Use of PK for Equivalence of OIPs



Day 2 Rotating Breakout Sessions

- **8.30 – 10.00 : Rotation 1**
- **10.30 – 12.00 : Rotation 2**
- **1.00 – 2.30 : Rotation 3**
 - Track A: **Considerations for Design of Equivalence Studies**
 - Track B: **In Vivo Tests (PK, PD and Biomarkers)**
 - Track C: **"In-Vitro Only" Equivalence**
 - Track D: **Device Design Similarity and Testing Needed to Support Device Changes in EU, US, Canada**

- **2:30 – 3:30 PM :**
 - **Panel moderators prepare summaries of breakout sessions.**
 - **Attendees leave with the Registration Desk any written questions for the Plenary Discussion**

- **3.30 – 5.00 : Reports from Breakout Sessions followed by Plenary Discussion and Q&A**



What's Next?

- Faculty will discuss the outcomes and next steps immediately following this workshop
- Presentations will be posted on the IPAC-RS and ISAM websites
- A report will be published



Housekeeping Items

- Please turn off cell phones
- Please complete the evaluation forms