

EUROPEAN EQUIVALENCE CONSIDERATIONS FOR ORALLY INHALED PRODUCTS (OIPs) FOR LOCAL ACTION

Frankfurt, Germany, 12-13 October 2010 (Tuesday-Wednesday)

Registration Desk: 6-7 PM on 11 October and from 7:30 AM on 12 October

Workshop Registration:
https://www.regonline.com/european_workshop_on_bioequivalence

Venue: Sheraton Frankfurt & Towers, Conference Center
Hotel Group Discount: www.starwoodmeeting.com/book/isamipacrs

Day One – Plenary Session (12 October 2010) Congress Center AB

REGULATORY PERSPECTIVES

Chairs: Gur Jai Pal Singh (Axar) and Dennis O'Connor (BI)

8:20-8:25 AM Introduction to Workshop

Sue Holmes, Co-Chair of the ISAM/IPAC-RS Organizing Committee (GSK, USA)

8:25-8:30 AM Welcome

Gerhard Scheuch, ISAM President (ActivAero, Germany)

8:30-9:00 AM Generic Medicines: Understanding the Legal Framework in the EU, US and Canada

Mary Devlin Capizzi (DBR, USA)

9:00-9:30 AM Experience with OIP Equivalence Determinations in the Netherlands - Focus on In-vitro Aspects

Marjolein Weda (RIVM, Netherlands)

9:30 – 10:00 AM MHRA/UK Experience – Focus on In-vivo, Design of Clinical Studies, Biomarkers, PK/PD

Sanjeeva Dissanayake (MHRA, United Kingdom)

10:00-10:30 AM MPA/Swedish Experience with OIP Equivalence Determinations

Eva Agurell (MPA, Sweden)

10:30-11:00 AM Coffee/Networking Break

11:00-11:30 AM Spanish Interpretation and Application of the OIP Guideline

Alfredo Garcia Arieta (Agency is Spanish Agency for Medicines and Health Care Products, Spain)

11:30 AM-12:00 PM Experience with Canadian Guidance: Similarity and Distinction Relative to European Approach

Myrna Dolovich (McMaster University, Canada)

12:00-12:30 PM An Overview of the FDA Position and Experience with Equivalence of Respiratory Drugs

Dale Conner (US FDA/CDER/OGD, Division of Bioequivalence, USA)

12:30-1:30 PM Complimentary Luncheon

INDUSTRY AND ACADEMIC PERSPECTIVES

Chairs: Terrence Tougas (Boehringer Ingelheim) and Michael Golden (Pearl Therapeutics)

1:30-2:00 PM Dose-Response and Related Mathematical Considerations

Gur Jai Pal Singh (Axar Pharmaceuticals, USA)

2:00 -2:30 PM Synopsis of the RDD/PQRI PK Workshop

Dennis O'Connor (Boehringer Ingelheim, USA)

2:30-3:00 PM Equivalence of OIPs in Europe: Present and Past Approval Principles

Anders Fuglsang (Consultant, Former Regulator, Denmark)

3:00-3:30 PM Coffee/Networking Break

3:30-4:00 PM Subject Populations and Study Designs

Richard Ahrens (University of Iowa, USA)

4:00-4:30 PM Review of the EMEA Guidelines' In-Vitro Equivalence Criteria for Cascade Impaction Data

Dennis Sandell (S5 Consulting, Sweden)

4:30-5:00 PM Use of In Vitro vs In Vivo Data To Conclude Equivalence of Two Inhaled Products

Dave Parkins (GSK, United Kingdom)

5:00-5:30 PM Some unresolved issues in the use of PK for equivalence of OIPs

Günther Hochhaus (University of Florida, USA)

Day Two (13 October 2010, 8:30 AM-5:30 PM)

Concurrent, rotating breakout sessions with plenary summary at the end. Complementary luncheon and coffee/tea breaks

Track A (Room 1020-1021)

Considerations for Design of Equivalence Studies

Moderators: Colin Reisner* (Pearl, USA); Richard Ahrens (University of Iowa, USA); Sanjeeva Dissanayake (MHRA, United Kingdom)

Track B (Room 1022-1023)

In Vivo Tests (PK, PD and Biomarkers)

Moderators: Gur Jai Pal Singh* (Axar, USA); Robert Hermann (Cr-Appliance, Germany); Dale Conner (FDA, USA); Param Nair (McMaster University, Canada)

Track C (Room 1024-1025): "In-Vitro Only" Equivalence

Moderators: Myrna Dolovich*(McMaster University, Canada); Bill Doub (FDA, USA); Dave Parkins (GSK, United Kingdom), Marjolein Weda (RIVM, Netherlands)

Track D (Room 1039-1040): Device Design Similarity and Testing Needed to Support Device Changes

Moderators: Dennis Sandell* (S5 Consulting, Sweden); Tim Chesworth (AstraZeneca, United Kingdom); Paul Lafferty (Medical Technology Consulting, UK); Robert Price (University of Bath, United Kingdom).

PLEASE FILL OUT ANONYMOUS SURVEY ON DEVICE CHANGES:
<http://www.keysurvey.com/survey/307433/1ae2/> Results will be discussed at the Workshop

TIMETABLE FOR DAY 2 (Wednesday, October 13, 2010):

8:30 – 10:00 AM Breakout Session – First Rotation (four concurrent tracks)

10:00 – 10:30 AM Coffee and Networking Break

10:30 – 12:00 PM Breakout Session – Second Rotation (four concurrent tracks)

12:00 – 1:00 PM Complimentary Luncheon

1:00 – 2:30 PM Breakout Session Third Rotation (four concurrent tracks)

2:30 – 3:30 PM Coffee and Networking Break FOR ONE HOUR. Breakout session moderators prepare summaries of their sessions, for the plenary wrap-up.

3:30 – 4:30 PM Reports from Breakout Sessions (15 minutes per track).

4:30-4:55 PM Plenary discussion of the Breakout Session Reports, Q&A

4:55 – 5:00 PM Final Remarks

Carole Evans, Co-Chair of the ISAM/IPAC-RS Organizing Committee (Inspire, USA)

5:00 PM - End of the public portion of the Workshop.

TIMETABLE FOR DAY 3 (October 14) – FACULTY ONLY: Room 1034-1035

8:30 AM – 3:00 PM

Discuss outcomes of the workshop, outline next steps (e.g., proposals for further research, publication of the conference report, etc.)

10:00 – 10:30 AM Morning Coffee Break

12:00 – 1:00 PM Complimentary Luncheon

2:30 – 3:00 PM Afternoon Coffee Break