Workshop Agenda

Wednesday, September 14, 2016

5:30 pm–7:00 pm
Registration

Thursday, September 15, 2016

7:00 am–6:00 pm ***Potomac Foyer***
Registration

8:30 am–9:00 am ***Potomac Foyer***
Welcome and Introductory Session

9:00 am–12:45 pm *Potomac Room*
SESSION I: *OUTCOME SUMMARY AND TYING UP LOOSE ENDS OF GBHI CONFERENCE 2015 IN AMSTERDAM*

Moderators
Mei-Ling Chen, Ph.D.
U.S. Food and Drug Administration, USA

Henning Blume, Ph.D.
SocraTec C&S, Germany

9:00 am–9:15 am
BCS-Based Biowaiver: Conclusions from Previous Panel Discussions at GBHI 2015 and Open Issues
Henrike Potthast, Ph.D.
BfArM, Germany

9:15 am–10:00 am
FDA Draft Guidance on BCS-Based Biowaiver 2015: New Regulations and Rationale
Mehul Mehta, Ph.D.
U.S. Food and Drug Administration, USA

9:30 am–10:00 am
BE Assessment of Different Strengths ("Strength Waiver"): Conclusions from Previous Panel Discussions at GBHI 2015 and Open Issues
Gerald Beuerle, Ph.D.
Teva, Germany

10:00 am–10:30 am
Experience with Application of SUPAC: Proportionality vs. Bracketing Approach
Angelica Dorantes, Ph.D.
U.S. Food and Drug Administration, USA

1**0:30 am–10:45 am** ***Potomac Foyer***
Beverage Break

10:45 am–11:15 am
Food Studies and Administration Conditions for IR products: Conclusions from Previous Panel Discussions at GBHI 2015 and Open Issues
Jan Welink, Ph.D.
Medicines Evaluation Board, The Netherlands

11:15 am–11:45 am
Scientific Approach to Suggestions for Harmonization
James Polli, Ph.D.
University of Maryland, USA

11:45 am–12:45 pm
Session I Panel Discussion

12:45 pm–1:45 pm ***Atrium***
Buffet Lunch
Complimentary to all attendees.

1:45 pm–6:00 pm *Potomac Room*
SESSION II: *PRODRUGS AND COMPOUNDS WITH PRE-SYSTEMIC EXTRACTION*

Moderators
Barbara Davit, Ph.D., J.D.
Merck & Co., Inc., USA

Alfredo Garcia, Ph.D.
Agencia Española de Medicamentos, Spain

1:45 pm–2:00 pm
Prodrugs: Current Regulatory Thinking and Open Issues: European Regulatory Authorities Perspective
Alfredo Garcia Arieta, Ph.D.
Agencia Española de Medicamentos, Spain

2:00 pm–2:15 pm
U.S. Food and Drug Administration Perspective
Nilufer Tampal, Ph.D.
U.S. Food and Drug Administration, USA

2:15 pm–2:30 pm
Chinese Regulatory Authority Perspective
Li Li, Ph.D.
China Food and Drug Administration, Chin0

2:30 pm–3:00 pm
Necessity to Measure Both the Parent Drug and Its Metabolite(s)
Helgi Jung Cook, Ph.D.
National Autonomous University, Mexico

Workshop Agenda continued

3:00 pm–3:30 pm
Situations(s) Where BE Assessment Should be Based on Metabolite Data (Only)
Murray Ducharme, Ph.D.
Learn/Confirm, Canada

3:30 pm–3:45 pm ***Atrium***
Beverage Break

3:45 pm–4:15 pm
Compounds with Pre-systemic Site of Action: Is the BE Concept Applicable?
Henning Blume, Ph.D.
SocraTec C&S, Germany

4:15 pm–4:45 pm
BE Assessment in Patient Population: Highly Variable Products with Critical Toxicological Profile
Barbara Schug, Ph.D.
SocraTec R&D, Germany

4:45 pm–5:45 pm
Session II Panel Discussion

5:45 pm–6:45 pm ***Atrium***
Cheese and Wine Reception
Complimentary to all attendees.

Friday, September 16, 2016

8:30 am–5:00 pm ***Potomac Foyer***
Registration

8:30 am–12:30 pm *Potomac Room*
SESSION III: *SCALING PROCEDURE AND ADAPTIVE DESIGN(S) IN BE ASSESSMENT OF HIGHLY VARIABLE DRUGS*

Moderators

Yu Chung Tsang, Ph.D.
Apotex, Canada

Andreas Brandt, Ph.D.
BfArM, Germany

8:30 am–8:45 am
Highly Variable Drugs: Current Regulatory Thinking and Open Issues: European Regulatory Authorities' Perspective
Andreas Brandt, Ph.D.
BfArM, Germany

8:45 am–9:00 am
U.S. Food and Drug Administration Perspective
Donald Schuirmann
U.S. Food and Drug Administration, USA

9:00 am–9:15 am
Highly Variable Drug Products: A Health Canada Perspective
Shereeni Veerasingham, MBBS, Ph.D.
Health Canada, Canada

9:15 am–9:45 am
Features, Constraints, and Extensions of the Scaling Approach
Lazlo Endrenyi, Ph.D.
University of Toronto, Canada

9:45 am–10:15 am
Adaptive Design Bioequivalence Studies: Controlling the Type 1 Error Rate while Preserving Power
Charlie DiLiberti
Montclair Bioequivalence Services, LLC, USA

10:15 am–10:30 am ***Atrium***
Beverage Break

10:30 am–11:00 am
Appropriate Statistical Procedures to Determine Adequate Alpha Needed for BE Assessment in Adaptive Design Studies Considering Fixed and Flexible Sample Sizes Per Group: Case Study
Barbara Davit, Ph.D., J.D.
Merck & Co., Inc., USA

11:00 am–11:30 am
Testing for Bioequivalence in Higher-Order Crossover Designs: Two-at-a-Time Principle Versus Pooled ANOVA
Pina D'Angelo
Novum Pharmaceutical Research Services, USA

11:30 am–12:30 pm
Session III Panel Discussion

Workshop Agenda continued

12:30 pm–1:30 pm *Atrium*
Buffet Lunch
Complimentary to all attendees.

1:30 pm–5:30 pm *Potomac Room*
SESSION IV*: EXCLUSION OF PK DATA IN BE ASSESSMENT OF IR AND MR PRODUCTS*

Moderators
Liang Zhao, Ph.D.
U.S. Food and Drug Administration, USA

Clive Wilson, Ph.D.
Sanofi, Germany

1:30 pm–1:45 pm
Exclusion of Plasma Profiles or Single PK Data from Statistical Assessment: Current Regulatory Thinking and Open Issues: European Regulatory Authorities Perspective
Jan Welink, Ph.D.
Medicines Evaluation Board, The Netherlands

1:45 pm–2:00 pm
U.S. Food and Drug Administration Perspective
Hao Zhu, Ph.D.
U.S. Food and Drug Administration, USA

2:00 pm–2:15 pm
Brazilian Regulatory Authority's Perspective
Gustavo Mendes Lima Santos, Ph.D.
ANVISA, Brazil

2:15 pm–2:45 pm
Potential Reasons for Exceptional Product Performance ("Outlier Profiles") in BE Studies
Keith D. Gallicano, Ph.D.
Novum Pharmaceutical Research Services, USA

2:45 pm–3:15 pm
How to Deal with "Event"-Related Outliers (e.g. Caused by AEs/Non-compliance)

3:15 pm–3:30 pm *Atrium*
Beverage Break

3:30pm–4:00 pm
How to Deal with Individual "Implausible" PK-Data in BE Studies?
Mohammad Khalil Mohammad, Ph.D.
ACDIMA Biocenter, Jordan

4:00 pm–4:30 pm
Pros and Cons for Re-dosing in Case of Outliers
Yu Chung Tsang, Ph.D.
Apotex, Canada

4:30 pm–5:30 pm
Session IV Panel Discussion

5:30 pm–5:45 pm
Conclusion and Future Perspective
Conference Co-chairs