April 12, 2018

08:00 - 09:00  Registration

09:00 - 09:10  Opening and welcome  
(Moderator: Henning Blume)  
Erem Bilensoy, EUFEPS President, Ankara TR  
Mehul Mehta, US Food and Drug Administration, Silver Spring MD USA

09:10 - 09:30  International Harmonization of BE Requirements - an EU perspective  
Tomas Salmonson, European Medicines Agency, Uppsala S

9:30 – 13:00  
Session I:  
Outcome summary and tying up loose ends of 2nd GBHI conference 2016 in Rockville/USA  
Session co-chairs:  
Henning Blume, SocraTec C&S, Oberursel DE  
Mei-Ling Chen, Washington DC USA

Prodrugs and compounds with pre-systemic extraction

09:30 - 09:45  Conclusions from previous discussions at GBHI 2016 and open issues  
Mei-Ling Chen, Washington DC USA

09:45 - 10:00  Suggestions for further harmonization of remaining open issues  
Henning Blume, SocraTec C&S, Oberursel DE

10:00 - 10:30  Discussion

10:30 - 11:00  Coffee and tea break

Scaling procedure and adaptive design(s)

11:00 - 11:15  Conclusions from previous discussions at GBHI 2016 and open issues  
Andreas Brandt, BfArM, Bonn DE

11:15 - 11:30  Suggestions for further harmonization of remaining open issues  
Lazlo Endrenyi, University Toronto CAN (to be confirmed)

11:30 - 12:00  Discussion

Exclusion of PK data in BE assessment

12:00 - 12:15  Conclusion from previous discussions at GBHI 2016 and open issues  
Wenlei Jiang, FDA, Silver Spring MD USA

12:15 - 12:30  Suggestions for further harmonization of remaining open issues  
Keith D. Gallicano, Novum Pharmaceutical Research, Pittsburgh USA

12:30 – 13:00  Discussion

13:00 - 14:00  Lunch break
Session II: Necessity of multiple dose studies in BE testing
Session co-chairs:
Gerald Beuerle, Teva, Ulm DE
Nilufer Tampal, US-FDA, Silver Spring MD USA

Introduction to Session II:

14:00 - 14:20  Similarities and differences between international guidelines
Gerald Beuerle, Teva, Ulm DE

14:20 - 14:35  Steady state studies in BE assessment - current US regulatory approach
Nilufer Tampal, US-FDA, Silver Spring MD USA

14:35 - 14:50  Justification of the current regulatory approach by EMA prohibiting the extrapolation of single dose BE to steady state in many cases
Alfredo Garcia, Agencia Española de Medicamentos, Madrid ES

14:50 - 15:20  Discussion

Invited Presentations:

15:20 - 15:40  Scientific arguments in favor and against the requirement to perform steady state studies for MR products
Murray Ducharme, Learn/Confirm, Montreal CAN

15:40 – 16:00  Discussion

16:00 - 16:30  Coffee and tea break

16:30 - 16:50  Primary and secondary PK metrics for evaluation of steady state studies, $C_{\text{min}}$ vs. $C_{\tau}$, relevance of $C_{\text{min}}/C_{\tau}$ or fluctuation for bioequivalence assessment
Helmut Schütz, BEBAC, Vienna AU

16:50 – 17:05  Discussion

17:05 - 17:25  Alternatives to steady state studies: Modelling/simulation or use of further parameters (e.g. partial AUC or plateau time) to better characterize plasma profiles after single dose administration
Yu Chung Tsang, Apotex, Toronto CAN

17:25 - 17:40  Discussion

17:40 - 18:30  Overall Discussion

19:00 - 22:00  Conference dinner
Session III: BE of Transdermal Delivery Systems
Session co-chairs: Barbara Schug, SocraTec R&D, Oberursel DE
Mehul Mehta, US Food and Drug Administration, Silver Spring MD USA

Introduction to Session Part I – bioequivalence and patch adhesion:

08:00 - 08:20 Bioequivalence and patch adhesion: similarities and differences between international guidelines
Barbara Schug, SocraTec R&D, Oberursel DE

08:20 - 08:35 Scientific arguments for the US perspective
Markham Luke, FDA, Silver Spring MD USA

08:35 - 08:50 Scientific arguments for the European perspective
Janet Schriever, BfArM, Bonn DE

08:50 – 09:20 Discussion

Invited Presentations:

09:20 - 09:40 Bioequivalence assessment for transdermal patches with diverging dosing intervals – Meaningful approaches for study design and selection of pharmacokinetic measures
Björn Schurad, Luye Pharma, Miesbach DE

09:40 - 09:55 Discussion

9:55 - 10:15 Coffee and tea break

10:15 - 10:35 Patch adhesion studies: evaluation and statistics
Martin Holz, Statistics Consultant, Tarp DE

10:35 - 10:50 Discussion

10:50 - 11:15 Skin irritation and sensitization studies: a medical appraisal of the currently applied guidelines
Walter Wigger-Alberti, Bioskin, Hamburg DE

11:15 - 12:00 Overall discussion with introductory statements
US-FDA perspective: Markham Luke, FDA, Silver Spring MD USA
EU regulatory authorities' perspective: Henrike Potthast, BfArM, Bonn DE

12:00 - 13:00 Lunch break
Session IV: Liposomal parenteral preparations
Session co-chairs:
Wenlei Jiang, US-FDA, Silver Spring MD USA
Henrike Potthast, BfArM, Bonn DE

Introduction to Session Part IV:
13:00 - 13:20 Liposome-based therapeutics: Impact of formulation on pharmacokinetics and pharmacodynamics
Alberto A. Gabizon, University Jerusalem IL

Wenlei Jiang, US-FDA, Silver Spring MD USA

13:35 - 13:50 Current EMA regulatory thinking regarding bioequivalence of liposomal products
Henrike Potthast, BfArM, Bonn DE

13:50 – 14:10 Discussion

Invited Presentations:
14:10 - 14:30 Necessity of determining released and encapsulated drug in liposomal parenteral formulations: 
Doxorubicin
Peter Langguth, University Mainz, Mainz DE

14:30 - 14:45 Discussion

14:45 - 15:05 Coffee and tea break

15:05 - 15:25 Relevance of non- dose-proportional PK and body surface-area adjusted dosing for BE assessment:
intra-individual exposure comparison and extrapolation between indications
Georg Hempel, University Münster DE

15:25 - 15:40 Discussion

15:40 - 16:00 Adequate criteria for assessment of bioequivalence for generic liposomal products
Daan Crommelin, University Utrecht NL

16:00 - 16:15 Discussion

16:15 - 16:50 Overall Discussion of Session IV

16:50 - 17:00 Closing remarks, Future of the Global Bioequivalence Harmonization Initiative