EUFEPS BABP Network

The Global Bioequivalence Harmonisation Initiative

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 **EMA's perspective on international harmonization of bioequivalence requirements**
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**

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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 **Justification of the current regulatory approach by US FDA including a general waiver of multiple dose studies in BE assessment**
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_{min} vs. C_{τ}, relevance of C_{min}/C_{τ} 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**

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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 **Necessity of multiple dose studies in case of patches with specific properties, i.e. formation of skin depots and varying dosing intervals (e.g. 3 vs. 4 days)**
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**

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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 **General concept for BE assessment of liposomal parenterals: which pharmacokinetic processes are determining?**
Alberto A. Gabizon, University Jerusalem IL

13:20 - 13:35 **North American regulatory authority's current regulatory thinking**
Wenlei Jiang, US-FDA, Silver Spring MD USA

13:35 - 13:50 **European regulatory authority's current regulatory thinking**
Henrike Potthast, BfArM, Bonn DE

13:50 – 14:10 **Discussion**

Invited Presentations:

14:10 - 14:30 **Necessity of determination of free and encapsulated (and total) drug, e.g. 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 **Generic liposome products: adequate bioequivalence criteria and therapeutic implications**
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**