EUFEPS BABP Network

The Global Bioequivalence Harmonisation Initiative

Programme March 22, 2015

19:00-21:00 **Registration and welcome reception**

Programme March 23, 2015

08:15 - 09:00 **Registration**

09:00 - 09:30 **Opening and welcome**
Meindert Danhof, EUFEPS President, Leiden NL
Jan Welink, Medicines Evaluation Board, Utrecht NL

09:30 - 10:00 **Introductory session - Why a global bioequivalence harmonisation initiative now?**
Henning Blume, SocraTec S&C, Oberursel DE

Session I: **Applicability BCS-based biowaiver: requirements and conditions**
Session co-chairs:
*Mehul Metha***,** US Food and Drug Administration, Washington DC USA
Henrike Potthast, BfArM, Bonn DE

10:00 - 10:15 **European regulatory authorities' perspective**
Henrike Potthast, BfArM, Bonn DE

10:15 - 10:30 **US-FDA perspective**
*Mehul Metha***,** US Food and Drug Administration, Washington D.C. USA

10:30 - 10:45 **Japanese regulatory authorities' perspective**
Chikako Yomota, National Institute of Health Sciences, JP

10:45 - 11:15 **Coffee and tea break**

11:15 - 11:45 **Differences in USA vs. EU approach: highest dose vs. highest dose strength; completeness of absorption vs. permeability; comparability of solid oral dosage forms**
*Jack Cook***,** Pfizer, Groton CT USA

11:45 - 12:15 **BCS-based biowaiver for Class-III drugs?**
Henning Blume, SocraTec S&C, Oberursel DE

Impact of excipients on systemic exposure

12:15 - 12:35 **What is evidence based?**
James Polli, University of Maryland, Baltimore MD, USA

12:35 - 12:55 **Result of experimental investigations**
Marlies Kubbinga, Medicines Evaluation Board, Utrecht NL

12:55 - 13:30 **Session I General discussion**

13:30 - 15:00 **Lunch break**

Session II: **Bioequivalence assessments of different strengths: presuppositions for extrapolation and bracketing**
Session co-chairs:
Gerald Beuerle, Teva, Ulm DE
Alfredo Garcia-Arieta, AEMPS, Madrid ES

Requirements for strengths waiver: current thinking and open issues

15:00 - 15:15 **European regulatory authorities' perspective**
Alfredo Garcia-Arieta, AEMPS, Madrid ES

15:15 - 15:30 **US-FDA perspective**
Mei-Ling Chen, FDA, Washington D.C. USA

15:30 - 15:45 **WHO perspective**
John Gordon, WHO, Geneva CH

15:45 - 16:00 **Japanese regulatory authorities' perspective**
Nahoko Kaniva, National Institute of Health Sciences, Tokyo JP

16:00 - 16:30 **Examples for selecting the "right" strength for bioequivalence studies based on linearity/proportionality, formulation category and solubility characteristics of the API**
Pavel Farkas, PLIVA, Zagreb HR

16:30 - 17:00 **Coffee and tea break**

17:00 - 17:30 **Industry experience with formulation requirements (proportionality/dissolution) for waiving bioequivalence studies for other dose strengths – North American concept and perspective**
Yu Chung Tsang, Apotex, Toronto CA

17:30 - 18:00 **Bracketing approach – an option for mono and fixed dose combination products?**
Gerald Beuerle, Teva, Ulm DE

18:00 - 18:30 **Session II General discussion**

19:30 - 22:00 **Conference Dinner**

Programme March 24, 2015

Session III: **Fasted vs. fed administration in bioequivalence studies for immediate release dosage forms**
Session co-chairs:
Henning Blume, SocraTec S&C, Oberursel DE
Jan Welink, Medicines Evaluation Board, Utrecht NL

Food studies in case of immediate release oral products current regulatory thinking and open issues

08:30 - 08:45 **European regulatory authorities' perspective**
Jan Welink, Medicines Evaluation Board, Utrecht NL

08:45 - 09:00 **US-FDA perspective**
*Mehul Metha***,** US Food and Drug Administration, Washington D.C. USA

09:00 - 09:15 **Indian pharmaceutical industry's perspective**
*Tausif Monif***;** Ranbaxy Laboratories Ltd, Guragon IN

09:15 - 09:45 **Reference product: clinical rationale of SmPC recommendations for administration in fed state and consequences for design of BE studies**
Barbara Schug, SocraTec R&D, Oberursel DE

09:45 - 10:15 **Impact of food composition on bioavailability**
Werner Weitschies, University of Greifswald, Greifswald DE

10:15 - 11:00 **Coffee and tea break**

11:00 - 11:30 **Necessity for studies in fasted and fed state in case of immediate release oral dosage forms?**
Barbara Davit, Merck Pharmaceuticals, Boston MA USA

11:30 - 12:00 **Session III General discussion**

12:00 - 13:00 **Future perspectives and closing discussion**
Mei-Ling Chen, FDA, Washington D.C. USA

13:00 - 14:00 **Farewell lunch**