

Final Programme

Monday, October 1, 2007

Welcome, Introduction and Opening Remarks

08:45–09:00

Daan JA Crommelin, EUFEPS President,
Leiden NL

Panos Macheras, Conference Co-Chair,
University of Athens, Athens GR

Session I: Physiological Factors affecting Drug Absorption

09:00–12:40

Session Leaders: *José A Morais*, University of Lisbon, Lisbon, PT & *Victor A Voicu*, Romanian Academy & University of Medicine and Pharmacy Carol Davila, Bucharest RO

09:00 Complexity of GI physiology and impact on drug absorption

Clive G Wilson, Strathclyde Institute for Pharmacy and Biomedical Sciences,
Glasgow Scotland UK

09:40 Site dependent drug absorption and impact on BA/BE assessment

Thomas Gramatté, Munich DE and
Frank Donath, SocraTec R&D, Oberursel DE

10:20 Coffee/Tea

10:50 Impact of food on drug absorption

Werner Weitschies, University of Greifswald, Greifswald DE

11:30 Formulation effects on drug absorption

Marcus E Brewster, Johnson & Johnson,
Beerse BE

12:10 Discussion – moderated by:

José A Morais, University of Lisbon, Lisbon, PT & *Victor A Voicu*, Romanian Academy & University of Medicine and Pharmacy Carol Davila, Bucharest RO

12:40 Lunch

Session II: Role of Pre-systemic Effects on Bioavailability

14:00-17:40

Session Leaders: *Constantin Mircioiu*, University of Medicine and Pharmacy, Bucharest RO & *Achiel Van Peer*, Johnson & Johnson, Beerse BE

14:00 Integrating the complexities of physiology and biology of GI tract into modelling the interindividual variability of oral drug absorption

Amin Rostami-Hodjegan, University of Sheffield and Simcyp Ltd, Sheffield UK

14:40 Assessment of intestinal and hepatic first-pass: Necessity to measure metabolites?

Henning H Blume, SocraTec R&D,
Oberursel DE

15:20 Coffee/Tea

15:50 Prediction of intestinal first-pass drug metabolism from *in vitro* data

Geoffrey T Tucker, University of Sheffield,
Sheffield UK

16:30 BCS and BDDCS

Leslie Z Benet, University of California,
San Francisco CA USA

17:10 Discussion – moderated by:

Constantin Mircioiu, University of Medicine and Pharmacy, Bucharest RO & *Achiel Van Peer*, Johnson & Johnson,
Beerse BE

17:40 **Demo Get-together: Delegates and Software Developers**

Software demonstration on physiologically-based absorption and bioavailability

Poster Session

19:30 **Welcome Reception Buffet**

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Tuesday, October 2, 2007

Session III: Impact of variability in BE studies

08:30–12:50

Session Leaders: *Vinod P Shah*, International Pharmaceutical Federation (FIP), North Potomac, MD USA & *Meir Bialer*, Hebrew University of Jerusalem, Jerusalem IL

08:30 Within subject variability: Design, determination & demonstration
Kamal K Midha, University of Saskatchewan and Pharmalytics Inc, Saskatoon CA

09:10 BE design considerations: Multiple dose versus single dose studies
Achiel Van Peer, Johnson & Johnson, Beerse BE

09:50 Can statistics address the BE for highly variable drugs?
Panos Macheras, University of Athens, Athens GR

10:30 Coffee/Tea

11:00 Current thinking of EMEA position on BE of Highly Variable Drugs
Tomas Salmonson, Medicinal Products Agency, Uppsala SE

11:40 Current Thinking of FDA on BE of Highly Variable Drugs
Barbara M Davit, FDA, Rockville MD USA

12:20 Discussion – moderated by
Vinod P Shah, International Pharmaceutical Federation (FIP), North Potomac MD USA & *Meir Bialer*, Hebrew University of Jerusalem, Jerusalem IL

12:50 Lunch

Session IV: Unresolved issues in BA/BE Regulations

14:00-16:00

Session Leaders: *Henning H Blume*, SocraTec R&D, Oberursel DE & *Panos Macheras*, University of Athens GR

Panel Members: *George Aislaitner*, National Organisation for Medicines, Athens GR, *Alfredo Garcia-Arieta*, Spanish Agency for Medicines and Health Care Products, Madrid ES, *Jan Welink*, Medicines Evaluation Board, The Hague NL

14:00 A series of 5-min BE issues presentations and discussion

Conclusions, recommendations and closing remarks

16:00-16:30

Panos Macheras, University of Athens, Athens GR