



Groupe de Métabolisme et de Pharmacocinétique

Association loi du 1er Juillet 1901 n° 22/2781

www.gmp.asso.fr

gmp@cines.fr

Journées des 24 & 25 Octobre 2013

Quantitative pharmacokinetic models

Three-dimensional approach: *in vitro*, *in vivo* and *in silico*

Approche quantitative en Pharmacocinétique

Une vision en 3D: *in vitro*, *in vivo* et *in silico*

Espace St Martin
199, Bis rue St Martin - 75003 PARIS



THURSDAY 24TH OCTOBER

Presentations (40' including Q&A)

08:30 – 09:00 Delegates Welcome

09:00 – 09:10 Foreword by the President

Emergence of transporters as key players in drug disposition

Chair: JM. Scherrmann (Université Paris V) & O. Barberan (GMP)

09:10 – 09:50 Transporters: from reality to where?
JM. Scherrmann, Inserm U705, UMR CNRS 8206, Université Paris V, France

09:50 – 10:30 Hepatic drug transporters: in vitro cellular models
O. Fardel, IRSET/UMR Inserm U1085, Université de Rennes, France

10:30 – 10:50 Coffee break
Poster session

10:50 – 11:30 Calibration of in vitro transport assay in drug development
A. Poirier, F. Hoffmann-La Roche Ltd., Basel, Switzerland

11:30 – 12:10 Transporters investigations in an industrial setting
D. Weitz, Sanofi-Aventis, Frankfurt Am Main, Germany

12:10 – 13:10 Lunch

13:20 – 13:40 **GMP GENERAL ASSEMBLY**

Integrated models for clearance and drug-drug interaction predictions

- Joint session with DMDG-

Chair: P. Kilford (DMDG), X Boulenc (GMP)

13:40 – 14:20 Investigations with the humanised CYP3A4 and CYP2D6 mouse models
E. Doyle, CXR Biosciences Ltd, UK

14:20 – 15:00 Interplay between transporters and metabolism and translation to human: challenges and examples.
T. Lavé, F. Hoffmann-La Roche Ltd., Basel, Switzerland

15:00 – 15:40 Predicting human hepatic clearance from in vitro metabolism and transport data.
KI. Umehara, Novartis Pharma AG, Basel, Switzerland

15:40 – 16:10 Coffee break
Poster session

16:10 – 16:50 Pharmacokinetics and Clinical Pharmacology over the years: Change in landscape, what next?
T. Shepard, MHRA, London, UK

16:50 – 17:30 Role of IVIVE and PBPK in prediction of clearance and DDI – Coming of Age
M. Jamei, Simcyp Limited, Sheffield, UK

17:30 – 18:10 Translational modelling of transporter-mediated pharmacokinetics and drug-drug interactions
A. Galetin, University of Manchester, UK

19:30 Social Event

FRIDAY 25TH OCTOBER

Presentations (40' including Q&A)

08:30 – 09:00 Delegates Welcome

Integrated modeling approaches for Clinical Development

Chair: V. Duval (GMP) & C. Laveille (Exprimo)

- 09:00 – 09:50 M&S, drug development and selection of optimal dose
C. Laveille, SGS Exprimo NV, Mechelen, Belgium & M. Tod, EA3738, Université de Lyon I, France
- 09:50 – 10:30 Modeling tools for antibody drug conjugates
J. Tibbitts, UCB Pharma Ltd., Slough, UK
- 10:30 – 11:10 Coffee break
Poster session
- 11:10 – 11:50 Use of biomarkers and tumor size translational modeling for oncology drug development
P. Girard, Merck Serono, Geneva, Switzerland
- 11:50 – 12:30 M&S : clinical uses and limits as witnessed by a clinical user
B. Boutouyrie-Dumont, Shire AG, Eysins, Switzerland
- 12:30 – 13:40 Lunch

Regulatory standpoint on quantitative Clinical Pharmacology

Chair: V. Aslanis (GMP)

- 13:40 – 14:20 Model based drug development: EMA experience and vision
E. Manolis, EMA, London, UK
- 14:20 – 15:00 Evolution of clinical pharmacology tools and topically administered drugs- Quo Vadis?
D. Bashaw, FDA, Silver Spring, USA
- 15:00 – 15:30 Short communications, Student Posters, Awards
Chair: L. Nguyen (GMP)

Use of quantitative approaches in Therapeutic Drug Monitoring

Chair: A. Schmitt (GMP)

- 15:30 – 16:20 TDM application in organ transplantation
P. Marquet, UMR Inserm U850, Université de Limoges, France
- 16:20 – 17:00 Bayesian forecasting for individualized dose therapy
S. Goutelle, UMR CNRS 5558, Université de Lyon I, France
- 17:00 Closing remarks