

# The Joint DMDG/GMP Open Meeting 2016

19 - 21 October, Espace St Martin, 199bis rue Saint Martin, 75003, Paris,  
France

## Wednesday 19th October

- 11-12:00     **Arrival, Registration & Lunch**
- 13:00        **Chairs' Opening Address**  
*Suzanne Iverson Hemberg, Sahlgrenska University Hospital, Sweden*  
*Vassilios Aslanis, Novartis, Switzerland*
- 13:30        **Keynote Speaker**  
*Prof Zoltan Takats, Ph.D, Imperial College London, UK*
- 14:30        Tea and coffee
- 14:50        **Session 1 – The impact of pre-clinical PKPD modelling on drug discovery and development**  
*Chairs: James Yates and Marc Trelu*
- Application of model based drug discovery from target idea to early clinical studies – a case study  
*Rasmus Jansson Löfmark, AstraZeneca R&D Mölndal, Sweden*
- Protein therapeutic PKPD (title to be confirmed)  
*Antje-Christine Walz, Roche, Switzerland*
- How early ePK-PD may help the drug discovery process with two case study in oncology & cardiovascular  
*Pierre-Yves Abecassis, Sanofi R&D, France*
- 17:00        **Poster Blitz** - 5-minute presentations from selected posters to engage audience prior to the poster session
- 17:45        **Poster Session**  
Wine and food available  
*Organisers: Peter Kilford, Florence Gattacceca and Sunil Mathur*
- 19:00        **End of session**

## Thursday 20th October

09:00

### **Session 2 – Implementing biodistribution to better understand PK**

*Chairs: Sherri Dudal; Graeme Clark and Florence Gattacceca*

Hunt for off-target binding - biodistribution and in vitro attempts to solve atypical PK

*Kevin Brady, F. Hoffman-La Roche, Switzerland*

Mass spectrometry imaging applied to investigating drug efficacy and toxicity across pharmaceutical R&D

*Richard Goodwin, AstraZeneca, UK*

Optimizing PK Stability of Therapeutics using Veltis-Albumin-Based Technologies – from rational design to PK/PD and biodistribution

*Jenny McLaughlan, Alumedix (formerly Novozymes), UK*

Ocular Drug Distribution and Elimination: Towards Improved Understanding with Modeling

*Arto Urtti, University of Helsinki, Finland*

10:30

Coffee

10:50

### **Session 3 – Skin Metabolism**

*Chair: Vibeke Hougaard Sunesen*

Contribution of dermal metabolism to local toxicities (Title to be confirmed)

*Simon Wilkinson, University of Newcastle, UK*

Drug metabolism in the skin: Relevance for development of dermally applied drug products

*Clemens Günther, Bayer, Germany*

Skin Metabolism: Comparison of In Vitro Methods and Models

*Carine Jacques-Jamin, Pierre-Fabre, France*

*In Vitro* Measurements to Determine Cutaneous Bioavailability

*Joan Eilstein, L'Oréal, France*

12:20

Lunch

13:50

### **Session 4 – New Approaches for the Prediction of ADME Parameters**

*Chairs: Angus Nedderman and Marion Millet*

Use of silensomes for reaction phenotyping (Title to be confirmed)

*Francoise Bree, Eurosafe, France*

Prediction of human hepatic clearance: role of drug metabolising enzymes and transporters in defining apparent intrinsic clearance

*Brian Houston, University of Manchester, UK*

Use of Upcytes to measure low clearance (Title to be confirmed)

*Michelle Schaefer, Boehringer Pharma, Germany*

- In silico approaches to metabolism prediction  
*Prof Robert Glen, Imperial College London, UK*
- 15:20 Tea and coffee
- 15:40 **Session 5 – Bioanalysis of Biomarkers: Challenges, pitfalls and new perspectives**  
*Chairs: Karelle Menochet & Tim Sangster*
- Biomarker strategy and bioanalytical challenges for biologics in preclinical drug discovery and development for use in PKPD  
*Sherri Dudal, UCB, UK*
- Presentation covering the EBF paper on biomarker validation and the outcome of the focussed workshop  
*Marianne Scheel Fjording, NovoNordisk, Denmark and Philip Timmerman, Janssen R&D, Belgium*
- 17:10 **Keynote Speaker**  
*Michael Eddleston, University of Edinburgh, UK*
- 18:00 **End of session**
- 19:30 **Conference Dinner & Entertainment**

### Friday 21st October

- 09:00 **Session 6 – PBPK application in clinical development to support regulatory submission**  
*Chairs: Antoine Deslandes and Sylvaine Cartot-Cotton*
- A Case of Regulatory Acceptance of PBPK Modelling Approach that Avoided Three Clinical DDI Studies  
*Venkatesh Pilla Reddy, AstraZeneca, UK*
- Physiologically-based pharmacokinetic modeling for prediction of drug-drug interactions: Eliglustat (Cerdelga®) as a case study  
*Vanaja Kanamaluru, Sanofi R&D, USA*
- Overview of use of PBPK in regulatory submissions (Title to be confirmed)  
*Speaker to be confirmed*
- 10:30 Tea and coffee
- 10:50 **Session 7 - The impact of Transporters in drug discovery: its not just about small molecules**  
*Chair: Mohammed Ullah*
- Transporter strategy in drug discovery and development: Understanding the impact of active transport on human pharmacokinetics  
*Karelle Menochet, UCB, UK*
- Assessing SM transporter interactions in vitro; refinement of assays and IVIVE  
*Mohammed Ullah, Roche, Switzerland*
- In vitro* systems to study impact of FcRN recycling and clearance IVVC  
*Simone Silke, Roche, Switzerland*

Impact of transporters on SSO's: case study with GalNac conjugated LNA  
targeting to the liver and PK/PD

*Erich Koller, Roche, Switzerland*

12:20

**Closing Remarks**

13:00

**Lunch and Delegates Depart**