DMDG past Open and Joint meeting programmes

Joint Meeting 2018
- in partnership with the SPS (Swedish Academy of Pharmaceutical Sciences)

16 - 18 October 2018 - Gothenburg, Sweden

Monday 15th October 2018

17.00-19.00 **Registration opens and drinks reception**

Tuesday 16th October 2018

08.00-09.00 **Registration continues**

09.00-09.15 **Chairpersons' Opening Address**
Rowan Stringer (Novartis) and Johanna Haglund (MetaSafe – an Admescope company)

09.15-10.45 **Session 1. Strategic collaborations. Pan European Industrial – Academic Partnerships**
Chair. Pawel Baranczewski, Uppsala University
Speakers.
1.1 What have industrial/academic partnerships ever done for us?
Steve Hood, GSK
1.2 Quantitative Systems Pharmacology is alive and well in the UK
James Yates, AstraZeneca
1.3 Academic–Industrial Partnerships in Drug Discovery-Opportunity or Foe for Academic Research. Comments from Academic Point of View
Pawel Baranczewski, UDOPP, Uppsala University

10.45-11.15 **Coffee, Posters, Trade Exhibition**

11.15-12.45 **Session 2. Strategic approaches to tissue quantification**
Chair. Johan Bylund, Medivir
Speakers.
2.1 To measure or not to measure? Tactics of tissue exposure assessment in drug research
Markus Fridén, AstraZeneca
2.2 Determination of total tumor concentrations in xenograft models; experiences from Merck oncology projects
Carl Petersson, Merck KGA
2.3 Bioanalytical aspects of tissue quantification, experiences from a Medivir oncology project
Rodrigo Palma Villar, Medivir

12.45-13.30 **Lunch, Posters, Trade Exhibition**

13.30-15.00 **Session 3. Strategies for PKPD Modelling in Drug Discovery and Development**
Chairs. Maria Kjellsson, Uppsala University
Speakers.
3.1 Preclinical PK/PD modelling to support First-in-Man trial in oncology
Sheila Annie Peters, Merck KGaA
3.2 Translational pharmacokinetic-pharmacodynamic modelling predicts human exposure-target engagement
Rasmus J. Löfmark, AstraZeneca
3.3 Using modelling & simulation throughout clinical drug development
Hanna Silber Baumann, F. Hoffmann-La Roche

15.00-15.30 **Coffee, Posters, Trade Exhibition**

15.30-16.30 **Session 4. Student Poster Blitz/ Rosenön award**
Chairs. Hugh Walton, Astex and Johanna Haglund, MetaSafe – an Admescope company

16.30-17.30 **Candlelight Keynote Speaker**
Chair. Rasmus Jansson Löfmark, AstraZeneca
Title. **Drugs, genes and precision medicine, a tour from RFLP to NGS**
Speaker. *Magnus Ingelman-Sundberg, Karolinska Institute*

17.30-19.30 **Poster Session**
Drinks Reception, Trade Exhibition
Chair. Hugh Walton, Astex (Hugh.Walton@astx.com)

19.30 **Dinner (Own Arrangements)**

Wednesday 17th October 2018

08.45-10.15 **Session 5. New Technologies in DMPK**
Chair. Mark Seymour, Covance
Speakers.

5.1 New Horizons in DMPK. The Next Wave of Automation
Scott Summerfield, GSK

5.2 The Application of Ion Mobility Mass Spectrometry in DMPK Workflows
Richard Clayton, Covance

5.3 Evaluation of transporter activity in stem cell derived renal models for drug clearance studies
Katarina Breitholtz, AstraZeneca

10.15-10.45 **Coffee, Posters, Trade Exhibition**

10.45-12.30 **Session 6. New Modalities – Part 1**
Chair. Lars Weidolf, AstraZeneca
Speakers.

6.1 Chemical Analysis and Physicochemical Characterization of Peptides - a Chemistry Perspective
Tomas Leek, AstraZeneca

6.2 ADME Characteristics of Semaglutide
Mette Lund Pedersen, NovoNordisk

6.3 ^{14}C-Labeling and Analysis Technologies to Enable Biologicals Drug Development
Wouter Vaes, TNO

6.4 Highlights from the 1st workshop of the Peptide ADME Discussion Group
Jesper Kammersgaard Christensen, NovoNordisk

12.30-13.30 **Lunch, Posters, Trade Exhibition**

13.30 **Session 7. New Modalities – Part 2**
Chair. Joanne Goodman, MedImmune
Speakers.

7.1 Bioanalytical Strategy for Locked Nucleic Acids (LNA) Therapeutics. Lessons Learned
Enric Bertran, F. Hoffmann-La Roche

7.2 Bioanalysis and Biodistribution of Dendrimer Nanoparticles
Eric Gangl, AstraZeneca

7.3 Discussion and Reflection Points from the EBF Focus Workshop on New Modalities. Science and Regulations Joining Hands
Philip Timmerman (on behalf of the European Bioanalytical Forum (EBF))

15.00 **Coffee, Posters, Trade Exhibition**

15.30 -17.00 **Session 8. Free Communicationss**
Chair. Graeme Scarfe, AstraZeneca
Speakers.

8.1 Target-mediated drug disposition for small molecules. an overlooked area?
Robert van Waterschoot, F. Hoffmann-La Roche

8.2 Application of in vitro parameters to predict non-linear absorption
Katie Haughan, AstraZeneca

8.3 The rise of Deuterated Drugs
Ray Cooke, Pharmaron

8.4 Development of a novel method to rapidly characterise uptake transporter activity in human hepatocytes in vitro. Applications and learnings
Oliver Light, UCB

17.30 -19.00 **Session 9. Debate. Lipinski Rules are no longer relevant – Future drugs will need to be >5 kDa if they are to become "profitable" medicines**
Ringmaster. Steve Hood, GSK

- Proposing - *Kevin Brady (UCB) and Ben Krippendorff (F. Hoffmann-La Roche)*
- Against - *Dennis Smith (DMDG Fellow) and Barry Jones (AstraZeneca)*

19.30-00.00 **Drinks Reception, Conference Dinner**

Thursday 18th October 2018

09.00-10.30 **Session 10. First In Human dose – regulatory and pharmacokinetic-pharmacodynamic considerations**

Chair. Rasmus J. Löfmark, AstraZeneca

Speakers.

10.1 The new EMA First In Human guideline
René Bouw, MPA

10.2 IQ MABEL. First In Human MABEL approach and Survey Results
Sherri Dudal, UCB

10.3 Integrated PKPD approach for the first-in-human dose selection of novel co-stimulatory cancer immunotherapies
Wouter Driessen, F. Hoffmann-La Roche

10.30-11.00 **Coffee, Posters, Trade Exhibition**

11.00-12.45 **Session 11. The Application of DDI and PBPK in Regulatory Environment**

Chair. Anna Nordmark, MPA

Speakers.

11.1 The use of Physiologically Based Pharmacokinetic Models for Regulatory Claims within EMA
Anna Nordmark, MPA

11.2 Physiologically based pharmacokinetic modelling current capabilities, case studies, and future opportunities. A Consortium Perspective
Venkatesh Pilla Reddy, AstraZeneca

11.3 Comparison Between the US FDA, EMA and Japan PMDA In Vitro DDI Guidances. Are we Closer to Harmonization?
Brian Ogilvie, Sekisui XenoTech

12.45-13.00 **Closing Remarks**

13.00-14.00 **Lunch and Delegates Depart**