Monday 15 <sup>th</sup> October	17:00 – 19.00 Registration opens, Drinks Reception	
Tuesday 16 <sup>th</sup> October	Wednesday 17 <sup>th</sup> October	Thursday 18 <sup>th</sup> October
08:00 – 09:00 Registration continues 09:00 – 09:15 Chairpersons Opening Address 09:15 – 10:45 Session 1: Strategic collaborations: Pan European Industrial – Academic Partnerships Chair: Pawel Baranczewski 10:45 – 11:15	08:45 – 10:15 Session 5 : New Technologies in DMPK Chair: Mark Seymour	09:00 – 10:30 Session 10 : First In Human dose – regulatory and pharmacokinetic-pharmacodynamic considerations Chair: Rasmus J Löfmark
	10:15 – 10:45 Coffee, Posters, Trade Exhibition	10:30 – 11:00 Coffee, Posters, Trade Exhibition
Coffee, Posters, Trade Exhibition 11:15 – 12:45 Session 2: Strategic approaches to tissue quantification	10:45 – 12:30 Session 6: New Modalities – Part 1 Chair: Lars Weidolf	11:00 – 12:45 Session 11: The Application of DDI and PBPK in Regulatory Environment Chair: Anna Nordmark
Chair: Johan Bylund		12:45 – 13:00 Closing Remarks
12:45 – 13:30 Lunch, Posters, Trade Exhibition	12:30 – 13:30 Lunch, Posters, Trade Exhibition	13:00 – 14:00 Lunch
13:30 – 15:00 Session 3: Strategies for PKPD Modelling in Drug Discovery and Development Chair: Maria Kjellsson	13:30 – 15:00 Session 7: New Modalities – Part 2 Chair: Jo Goodman	
15:00 – 15.30 Tea, Posters, Trade Exhibition	15:00 – 15:30 Tea, Posters, Trade Exhibition	
15:30 – 16:30 Session 4: Student Poster Blitz/ Rosenön award Chairs: Rowan Stringer and Johanna Haglund	15:30 – 17:00 Session 8: Free Communications Chair: Graeme Scarfe	
16:30 – 17:30 Candlelight Keynote Speaker: Magnus Ingelman-Sundberg, Karolinska Institute Chair: Rasmus J. Löfmark	17:30 – 19:00 Session 9: <b>Debate:</b> Lipinski Rules are no longer relevant – Future drugs will need to be >5 kDa if they are to become "profitable" medicines Chair: Steve Hood	Delegates Depart
17:30 – 19:30 Poster Session Trade Exhibition Drinks Reception 19:30 Dinner (Own Arrangements)	19:30 – 00:00 Drinks Reception, Conference Dinner	

# Monday 15th October

# <u>17:00 – 19:00:</u>

Registration opens, Drinks Reception

# Tuesday 16th October

# <u>08:00 - 09:00:</u>

**Registration continues** 

# <u>09:00 - 09:15:</u>

Chairpersons Opening Address: Rowan Stringer (Novartis) and Johanna Haglund (MetaSafe – an Admescope company)

### <u>09:15 – 10:45:</u>

- Session 1: Strategic collaborations: Pan European Industrial Academic Partnerships
- Chair: Pawel Baranczewski, Uppsala University

### Speakers:

- What have industrial/academic partnerships ever done for us? Steve Hood, GSK
- Quantitative Systems Pharmacology is alive and well in the UK James Yates, AstraZeneca
- Academic–Industrial Partnerships in Drug Discovery-Opportunity or Foe for Academic Research. Comments from Academic Point of View
  Barran acaustic Solities of DDD, ADM5-T(UDODD, Uppedia University)

Pawel Baranczewski, SciLifeLab DDD, ADMEoT/UDOPP, Uppsala University

# <u>10:45 – 11:15</u>

Coffee, Posters, Trade Exhibition

# <u>11:15 – 12:45</u>

- Session 2: Strategic approaches to tissue quantification
- Chair: Johan Bylund, Medivir

# Speakers:

- To measure or not to measure? Tactics of tissue exposure assessment in drug research Markus Fridén, AstraZeneca
- Determination of total tumor concentrations in xenograft models; experiences from Merck oncology projects *Carl Petersson, Merck KGaA*
- Bioanalytical aspects of tissue quantification, experiences from a Medivir oncology project *Rodrigo Palma Villar, Medivir*

# <u>12:45 – 13:30</u>

Lunch, Posters, Trade Exhibition

# <u>13:30 – 15:00</u>

Session 3:	Strategies for PKPD Modelling in Drug Discovery and Development
<b>.</b>	

Chair: Maria Kjellsson, Uppsala University

Speakers:

- Preclinical PK/PD modelling to support First-in-Man trial in oncology *Sheila Annie Peters, Merck KGaA*
- Translational pharmacokinetic-pharmacodynamic modelling predicts human exposure-target engagement *Rasmus J. Löfmark, AstraZeneca*
- Using modelling & simulation throughout clinical drug development Hanna Silber Baumann, F. Hoffmann-La Roche

# <u>15:00 - 15.30</u>

Tea, Posters, Trade Exhibition

# <u>15:30 - 16:30</u>

Session 4:	Student Poster Blitz/ Rosenön award
Chair:	Rowan Stringer, Novartis and Johanna Haglund, MetaSafe – an Admescope company

<u>16:30 – 17:30</u> Candlelight Keynote Speaker Chair:Rasmus Jansson Löfmark, AstraZenecaSpeaker:Magnus Ingelman-Sundberg, Karolinska InstituteTitle:Drugs, genes and precision medicine, a tour from RFLP to NGS

<u>17:30 – 19:30</u> Poster Session

<u>19:30</u> Dinner (Own Arrangements)

# Wednesday 17th October

# <u>08:45 - 10:15</u>

Session 5:New Technologies in DMPKChair:Mark Seymour, Covance

Speakers:

- New Horizons in DMPK: The Next Wave of Automation Scott Summerfield, GSK
- The Application of Ion Mobility Mass Spectrometry in DMPK Workflows *Richard Clayton, Covance*
- Evaluation of transporter activity in stem cell derived renal models *Katarina Breitholtz, AstraZeneca*

<u>10:15 – 10:45</u>

Coffee, Posters, Trade Exhibition

# <u> 10:45 – 12:30</u>

- Session 6: New Modalities Part 1
- Chair: Lars Weidolf, AstraZeneca

# Speakers:

- Chemical Analysis and Physicochemical Characterization of Peptides a Chemistry Perspective *Tomas Leek, AstraZeneca*
- ADME Characteristics of Semaglutide Mette Lund Pedersen, NovoNordisk
- <sup>14</sup>C-Labeling and Analysis Technologies to Enable Biologicals Drug Development Wouter Vaes, TNO
- Highlights from the 1<sup>st</sup> workshop of the Peptide ADME Discussion Group Jesper Kammersgaard Christensen, NovoNordisk

<u>12:30 - 13:30</u>

# Lunch, Posters, Trade Exhibition

# <u>13:30 - 15:00</u>

- Session 7: New Modalities Part 2
- Chair: Joanne Goodman, MedImmune

Speakers:

- Bioanalytical Strategy for Locked Nucleic Acids (LNA) Therapeutics: Lessons Learned Enric Bertran, F. Hoffmann-La Roche
- Bioanalysis and Biodistribution of Dendrimer Nanoparticles *Eric Gangl, AstraZeneca*
- 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))*

<u>15:00 - 15:30</u>

Tea, Posters, Trade Exhibition

#### Graeme Scarfe, AstraZeneca

#### Chair: Speakers:

- Target-mediated drug disposition for small molecules: an overlooked area? *Robert van Waterschoot, F. Hoffmann-La Roche*
- Application of in vitro parameters to predict non-linear absorption Katie Haughan, AstraZeneca
- The rise of Deuterated Drugs Ray Cooke, Pharmaron
- Development of a novel method to rapidly characterise uptake transporter activity in human hepatocytes in vitro: Applications and learnings
  Oliver Light, UCB/ University of Bath

# <u>17:30 – 19:00</u>

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

### Speakers:

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

# <u>19:30 - 00:00</u>

Drinks Reception, Conference Dinner

# Thursday 18th October

### <u>09:00 - 10:30</u>

Session 10:First In Human dose – regulatory and pharmacokinetic-pharmacodynamic considerationsChair:Rasmus J. Löfmark, AstraZeneca

#### Speakers:

- The new EMA First in Human guideline *René Bouw, MPA*
- IQ MABEL: First In Human MABEL approach and Survey Results Sherri Dudal, F. Hoffmann-La Roche
- Integrated PKPD approach for the first-in-human dose selection of novel co-stimulatory cancer immunotherapies *Wouter Driessen, F. Hoffmann-La Roche*

# <u>10:30 - 11:00</u>

Coffee, Posters, Trade Exhibition

# <u>11:00 - 12:45</u>

Session 11:The Application of DDI and PBPK in Regulatory EnvironmentChair:Anna Nordmark, Scandinavian Development Services

# Speakers:

- The use of Physiologically Based Pharmacokinetic Models for Regulatory Claims within EMA Anna Nordmark, Scandinavian Development Services
- Physiologically based pharmacokinetic modelling current capabilities, case studies, and future opportunities: A Consortium Perspective

Venkatesh Pilla Reddy, AstraZeneca

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

<u>12:45 – 13:00</u>

**Closing Remarks** 

<u>13:00 – 14:00</u> Lunch and depart