

Optimizing the Use and Interpretation of *In Vitro* ADME Studies

2008 Seminar series on IVIVE

CONFIRMED DATES
 The 9th Simcyp Consortium Meeting & Interactive Workshops
 Sept 2008
 Sheffield, UK



BOSTON, USA

Hyatt Regency

 3rd June 2008

Alex Avdeef - Co-founder and President, pION Inc., Woburn, MA, USA "Prediction of oral drug absorption: Everything should be made as simple as possible, but not simpler"

Kim L R Brouwer - Professor and Chair, Pharmacotherapy and Experimental Therapeutics, University of North Carolina, NC, USA "Use of sandwich-cultured human hepatocytes to predict hepatobiliary drug clearance and transporter mediated DDI"

Michael H Court - Assistant Professor of Pharmacology and Experimental Therapeutics, Tufts University, MA, USA "Interindividual variability in drug glucuronidation"

Ryosei Leo Kawai - Senior Expert Modeller, M&S, Novartis, Institute for Biomedical Research Inc., Cambridge, MA, USA "Integrating PBPK and PKPD to facilitate decision-making in drug development"

Soraya Madani - Director, Drug Regulatory Affairs, Novartis FDA Liaison and Policy Office, Rockville, MD, USA "Critical evaluation of revised FDA draft guidance for drug-drug interaction (DDI) studies"

Lisa von Moltke - Senior Director, Millennium Pharmaceuticals, Cambridge, MA, USA "Clinical pharmacology: Making sense of translational information"

R Scott Obach - Senior Research Fellow, Pfizer Global R&D, Groton, CT, USA "An update on prediction of drug-drug interactions: An industrial point of view"

K Sandy Pang - Professor of Pharmacy & Pharmacology, University of Toronto, Canada "The role of vitamin D receptor (VDR) on transporters and enzymes"

Shashank Rohatagi - Senior Director, M&S, Transitional Medicine & Clinical Pharmacology, Daiichi Sankyo, Edison, NJ, USA "Model-based drug development"

Jash Unadkat - Professor of Pharmaceutics, University of Washington, WA, USA "Complexity of DDI caused by anti-HIV drugs: The role of transporters and metabolic enzymes"

Barry Jones - Senior Director, PDM, Pfizer, Sandwich, UK "The importance of understanding clearance routes in the simulation of clinical drug-drug interactions from *in vitro* systems"

For further information and details on how to register please visit www.simcyp.com or contact k.jkinson@simcyp.com

SAN FRANCISCO, USA

The Fairmont

 5th November 2008

Leslie Z. Benet - Professor of Biopharmaceutical Sciences UCSF, San Francisco, CA, USA "*In vitro* results and BDDCS in predicting transporter effects on drug absorption, disposition and DDIs of NMEs"

Volker Fischer - Senior Director DMPK and Bioanalysis, Abbott, IL, USA "PBPK vs Allometry: Case examples for predicting human PK during compound selection and early development"

Andrew Parkinson - Founder & CEO XenoTech, Lenexa, KS, USA "Induction of drug-metabolizing enzymes: *In vitro* studies, IVIVE and the emerging role of xenosensors in endobiotic homeostasis"

Ravi Rahavendran - Associate Director, Pharmacokinetics, Dynamics and Metabolism Department, Pfizer Global R&D, La Jolla, CA, USA "Simcyp as a risk prediction and assessment tool in drug discovery and development - selected case examples"

Malcolm Rowland - Professor Emeritus, School of Pharmacy and Pharmaceutical Sciences, University of Manchester, UK "Predicting human Pharmacokinetics: How are we doing?"

Magang Shou - Director of Pharmacokinetics and Drug Metabolism, Amgen Inc. Thousand Oaks, CA, USA "Kinetic approaches and correlation analyses for prediction of clinical drug interactions from *in vitro* CYP3A4 induction data"

Donald Stanski - MD, Global Head Modelling and Simulation, Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA "Creating an integrated modelling and simulation department: lessons learned"

Geoff Tucker - Professor, Academic Unit of Clinical Pharmacology, University of Sheffield, UK "All models are wrong - but some are useful"

John A. Wagner - MD, PhD Executive Director, Clinical Pharmacology, Merck Research Laboratories, Acting Scientific Discipline Integrator, Merck SIMS Rahway, NJ, USA "Strategically Integrated Modelling and Simulation (SIMS) in early and late drug development"

Diane Wang - Director, Clinical Pharmacology, Oncology, Pfizer Global R&D, La Jolla, CA, USA "Application of modelling and simulation in pre-clinical and clinical drug development - case examples"

Walter Woltosz - Chairman & CEO, Simulations Plus, Inc., CA, USA "Overcoming skepticism in widespread use of M&S in drug discovery and development - 11 years of experience in Simulation Plus"

Interactive workshop on Concepts of IVIVE

 BOSTON - 1st + 2nd June 2008

 SAN FRANCISCO - 3rd + 4th November 2008

Interactive workshop on Applications of IVIVE

 BOSTON - 4th + 5th June 2008

 SAN FRANCISCO - 6th + 7th November 2008

The two day workshops will take place prior to and after each of the seminars, led by Professor Amin Rostami of the University of Sheffield

These workshops cover aspects of *in vitro* - *in vivo* extrapolation (IVIVE) in the prediction of absorption, distribution, clearance and drug-drug interactions.

The courses are designed to give a general background to PBPK and IVIVE involving prediction of concentration-time profiles. All course material is set within a context relevant to drug discovery and development. All courses involve computer-based hands-on problem solving sessions.

Due to the success of the previous workshops in Philadelphia, Basel, Baltimore, Prague, Arosa and high demand for these interactive workshops, we recommend early booking.