



Welcome to

Hands on workshop on physiological modelling of therapeutic proteins

Workshop Agenda

October 8-9, 2020

Day 1 – Thursday 8th October 2020

09:00	Introduction to pharmacokinetics of therapeutic proteins
09:30	Distribution of therapeutic proteins
10:15	Biologics Simulator Demo
10:45	Hands on exercises – proteins distribution
11:15	Clearance of therapeutic proteins
11:45	Hands on exercises – proteins clearance
12:30	Lunch Break
13:30	PBPK modelling of mAbs: FcRn recycling models
14:30	Hands on exercises – PBPK modelling of monoclonal antibodies (mAbs)
15:30	Finish

Day 2 – Friday 9th October 2020

09:00	Target Mediated Drug Disposition (TMDD)
09:45	Hands on exercises - TMDD models
10:30	PBPK modelling of Antibody Drug Conjugates (ADCs)
11:30	Hands on exercises – PBPK models for ADCs
12:15	Lunch Break
13:30	Administration of biologics in eyes
14:30	Discussions and wrap up
15:00	Finish

Tutors:



Dr Iain Gardner (Vice President, Head of Translational DMPK Science)

After qualifying as a Pharmacist, Iain received his PhD from the University of Sheffield in 1993 for a thesis examining structure activity relationships for hepatic uptake and biliary clearance of drugs.

Since July 2011, Iain has been Head of the Translational DMPK Science team within Certara UK Limited's Simcyp Division. The science team at Simcyp is responsible for further developments of the population based physiologically based PK-PD simulators to meet the needs of Simcyp consortium members.

Prior to joining the Simcyp team, Iain spent 12 years working in the Pharmacokinetics, Dynamics and Metabolism Department at Pfizer Global Research & Development in the UK and the US. In this role he was responsible for optimising pharmacokinetics (PK) properties of compounds for Drug Discovery projects and resolving any ADME issues for projects later in Development. Particular areas of interest were prediction of human PK and application of *in silico* physiologically based PK approaches to projects.

Before joining Pfizer Iain worked as a post-doctoral scientist at the University of Toronto, Canada and Imperial College, UK investigating the links between the metabolism and toxicity of drugs and chemicals.



Masoud Jamei is the Senior Vice President of Research and Development at Certara UK Limited's Simcyp Division where he works with a team of around 40 scientists and 15 developers focusing on the design, development and implementation of various aspects of systems pharmacology models including *in vitro-in vivo* extrapolation linked Physiologically-based PK/PD models of small and large molecules and applying data analysis techniques to PBPK models in healthy and patient populations. He has been the author or co-author of over 50 manuscripts and book chapters and 160 abstracts. He

joined the company in 2003.



Anam Fayyaz is a PhD student at Certara UK Limited's Simcyp Division with Dr Masoud Jamei (Vice President of R&D, Simcyp Division) and Dr Iain Gardner (Senior Scientific Advisor and Head of Translational Science (DMPK), Simcyp Division) as her industrial supervisors. Anam is a pharmacist by background and did her Master's degree in General Toxicology and Environmental Risk Assessment from the University of Eastern Finland, Finland. Anam's master's thesis was in drug metabolism where she studied enzyme kinetics and drug-drug interactions

for coumarin compounds. Her PhD work is to develop physiological based system pharmacological models for the rabbit and human eye. Anam is gaining expertise in *In vitro In vivo* extrapolation (IVIVE), QSPR data analysis, *In vitro* cell culture techniques, *in vivo* pharmacokinetic experimental techniques pharmacokinetic / pharmacodynamics modelling for small molecules.