GMP
Groupe de Métabolisme et Pharmacocinétique

Physiologically based Pharmacokinetic (PBPK) Modeling
8-9 December 2022 – Marseille (France)

This 2-day workshop is co-organized by the **directors of the Master 2 in PK** (Lyon, Marseille, Paris, Rennes and Toulouse), **PhinC Development** and the **GMP**.

For registration and information, please contact Fabrice Hurbin (fabrice.hurbin@sanofi.com)

Workshop overview and objectives

This workshop is designed to provide participants with the necessary information needed for Physiologically Based Pharmacokinetic (PBPK) modeling. New Chemical and Biological Entities will be considered when applicable.

The workshop has been structured into two parts:

- 1st day: four keynote lectures (90 minutes each) on the main applications of PBPK (including case studies)
- 2nd day: full day of hands-on exercises.

Agenda

Thursday 8 December 2022: Keynote lectures

Time	Title	Speakers
9:45 - 9:50	Welcome	***GMP***
09:50 - 11:20	**Prediction of human pharmacokinetics from preclinical data** • Cross species extrapolation in PBPK • Use of in vitro data to predict Pharmacokinetics • Use of in vitro data to predict Pharmacodynamics	***Donato Teutonico*** *(Sanofi)*
11:20 - 11:45	Coffee break	
11:45 - 13:15	**Biopharmaceutic** • Food effect prediction • Formulation optimization • IVIVC with PBPK	***Letizia Carrara*** *(Servier)*
13:15 - 14:15	Lunch	
14:15 -15:45	**Special populations** • Maternal PBPK modeling • Lactational PBPK modeling	***Marc Codaccioni*** *(Certara)*
15:45 - 16:15	Coffee break	
16:15 - 17:45	**Environmental & toxicologic applications** • Development of PBPK models for data-poor chemicals • Interpretation of human biomonitoring data • Derivation of regulatory thresholds	***Céline Brochot*** *(INERIS)*
From 18:30	Cocktail	

GMP

Groupe de Métabolisme et Pharmacocinétique

Friday 9 December 2022: Hands-on exercises

<table>
<tr><th>Time</th><th colspan="2">Title</th><th>Facilitators</th></tr>
<tr><td>8:30 - 12:30*</td><td colspan="2">Building a PBPK model
Case study of hydrocodone (CYP3A4 and CYP2D6 substrate)
Modeling of parent drug and metabolite</td><td rowspan="4">Florence Gattacceca (Aix-Marseille Université)

Kahina Haouchine (PhinC)

Jeremy Perrier (PhinC)</td></tr>
<tr><td>12:30 - 14:00</td><td colspan="2">Lunch</td></tr>
<tr><td rowspan="2">14:00 - 17:30*</td><td>Subgroup 1
(15 delegates)</td><td>Subgroup 2
(15 delegates)</td></tr>
<tr><td>Biopharmaceutic applications
Modeling extended release (ER) tablets using in vitro data
Prediction of exposure with different ER tablets</td><td>DDI applications
Case study with paroxetine, a strong inhibitor of CYP2D6</td></tr>
</table>

* Including a coffee break

Number of participants

- 20 students registered in one of the 5 Master 2 co-organizing this workshop
- 10 industrial/academic delegates

Registration fees (including lunch, coffee breaks and cocktail)

- Student rate: free registration
- Industrial/academic rate: 750 € (700 € for registration + 50 € for GMP membership)

Location

- Campus Saint-Charles, 3 place Victor Hugo, 13003 Marseille (400 m from Saint-Charles train station)

Software

- The different softwares used in PBPK will be presented (GastroPlus®, MC Sim, PK-SIM®, and SimCYP®).
- The hands-on exercises will be performed with GastroPlus®

Requirements

Delegates are required to bring a laptop computer and will be provided with free access to GastroPlus® for the duration of the workshop. No prior experience with GastroPlus® is required. However, delegates will be invited to follow tutorials for a faster handling of the software.

GMP

Groupe de Métabolisme et Pharmacocinétique

Speaker Biography

Donato Teutonico (PharmD, PhD - Sanofi)

Donato Teutonico has received his PharmD from the University of Turin, Italy, where he specialized in chemical and pharmaceutical technology, and his PhD in pharmaceutical sciences from Paris-South University, France. He has 13 years of experience in modeling and simulation of drug effects and clinical trials in industrial and academic settings. Donato has authored 2 books, 2 book chapters and contributed to more than 13 publications in international journals. He is currently PBPK Scientific Expert at Sanofi.

Letizia Carrara (PhD - Servier)

Letizia Carrara is a Senior Pharmacometrician in the Clinical Pharmacometrics group at Servier, in Paris. She is an Engineer and in 2018 she received a PhD in Bioengineering and Bioinformatics at the University of Pavia (Italy). During the PhD she worked on several projects, both in preclinical and clinical settings, in oncology and infectious diseases, and she spent 6 months as a visiting scientist at the University College of London (UCL). She has 4-year experience as a pharmacometrician, and her main areas of expertise are Physiologically-Based Pharmacokinetic (PBPK) modelling for first time in human (FTIH) predictions, drug-drug interaction (DDI) simulations, IVIVC, dosing in special populations, absorption modelling and food effect predictions in oncology and CNS diseases

Marc Codaccioni (PhD - Certara)

Marc Codaccioni received a PhD in Toxicology from AgroParisTech engineering school in 2020. His thesis subject allowed him to work in the maternal and fetal exposure to xenobiotics field through PBPK modelling techniques. He worked as PBPK modeler at PhinC Development before joining the French health drug regulatory authority as drug interactions assessor. Marc is now Research Scientist II at Certara UK, where he is involved in several projects dealing with modeling and simulation in sensitive population.

GMP

Groupe de Métabolisme et Pharmacocinétique

Céline Brochot (PhD, INERIS)

Dr Céline Brochot PhD. in biomathematics (University of Paris VI, France), is an expert in toxicokinetic modeling and risk assessment. She has more than 15 years of experience in the fields of physiologically based pharmacokinetic models, exposure assessment and in vitro/in vivo extrapolations for toxicokinetics. She is involved in several national and international projects. She leads or led WP on toxicokinetic modelling in several European projects on integrated risk assessment (2FUN, 4FUN and OBERON) and was the task leader on exposure assessment using PBPK modelling in the European project HELIX on human early-life exposome. She is an expert for the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) on toxicokinetic modelling.

Facilitator Biography

Florence Gattacceca (PharmD, PhD, HDR - Aix-Marseille Université)

Florence Gattacceca is an Associate Professor at Aix-Marseille University, director of the Master Program in Pharmacokinetics. Her reseach, in the COMPO group (COMPutational pharmacology and clinical Oncology), focuses on improvement of cancer treatment through optimization of administration and delivery of existing drugs using modelling and simulation strategies. She obtained her PharmD in 1999 in Paris V - René Descartes University (France) and her PhD in Paris XII - Créteil University (France). She joined Montpellier University in 2007 as an assistant professor in Pharmacokinetics, spent a 1-year sabbatical in Northeastern University (Boston, USA) in 2012-2013, and joined the school of pharmacy of Marseille in 2017. In addition to teaching and research activities, Florence Gattacceca is also an external pharmacokinetics expert for ANSM (French national agency for drugs).

GMP

Groupe de Métabolisme et Pharmacocinétique

Kahina Haouchine (PharmD, PhinC Development)

Kahina Haouchine is a pharmacometrician and PBPK Specialist at PhinC Development since 2020. Before joining the company, Kahina worked for UCB Pharma on many clinical projects (NDA submission, specific population, drug-drug interactions, etc.) and preclinical Discovery including First-In-Human prediction of small molecules. Kahina holds a Pharmacy degree and a master's degree in pharmacokinetics from the University of Paris Descartes.

Jérémy Perrier (PharmD, PhD - PhinC Development)

Jérémy Perrier is a pharmacometrician specialized in PBPK at PhinC Development. He completed his PhD in 2018 at the University of Strathclyde (Glasgow, Scotland) where he worked on various projects involving the development of advanced in vitro and in silico tools for the characterization of oral drug solubility. Then he joined PhinC Development where he developed a broad PBPK experience by working on several projects such as DDI predictions, first in man predictions, formulation studies and also new applications such as modeling of intra-articular administration. Jérémy holds a Pharmacy degree from the University of Aix-Marseille (2012), and a master's degree in pharmacokinetics from the University of Paris Descartes (2013).