



Pharmacokinetic Drug-Drug interaction assessment workshop 26th-28th November 2025 – Sanofi Montpellier (France)

This 2-day workshop is co-organized by the **directors of the Master 2 in PK** (from universities of Lyon, Marseille, Paris and Toulouse), AFPT/**Club Phase1** and the **GMP**.

For registration, <u>Events – Association GMP - Groupe de Métabolisme et</u> Pharmacocinétique

For information, please contact contact@gmp.asso.fr or Olivier Nicolas (Olivier.nicolas@sanofi.com)

Workshop overview and objectives

This workshop is designed to provide to participants the necessary information needed to perform pharmacokinetic Drug-Drug interaction assessment. New Chemical and Biological Entities will be considered when applicable.

Agenda

Time	Title	Speakers	
Wednesday			
13:30 - 13:35	Welcome	GMP/AFPT-CP1	
13:35 - 15:05	 Review of ICH guidances/guidelines In vitro test Strategy to assess in vitro DDI risk DDI static prediction 	Priscilla Brun (Sanofi)	
15:05 - 15:30	Coffee break		
15:30 – 17:30	Hands-on Drug-Drug Interaction on in vitro approaches • DDI static predictions (including examples)	Priscilla Brun/Olivier Nicolas (Sanofi)	
Thursday			
9:00 – 10:30	Mechanistic static approach • Pharmapendium	Olivier barberan (pharmapendium)	
10:30 - 11:00	Coffee break		
11:00 - 13:00	Overview building and qualification PBPK model Prediction for a drug as victim and as perpetrator	Mailys De Sousa Mendes (simcyp certara)	
13:00 – 14:00	Lunch		





Time	Title	Facilitators
Thursday		
14:00 - 15:30*	Building a PBPK model to predict DDI Demo: prediction for a drug as victim and as perpetrator	Mailys De Sousa Mendes (simcyp certara)
15:30-16:00	Coffee break	
16:00-18::00	 Clinical DDI studies Study design: to which answers we want to reply What other interactions than PK DDI Examples- focus on strategy with: ->Cytochrome -> transporter 	Henri Caplain/Yves Donazzolo (AFPT)/ Isabelle Deprez (GMP/Certara)
19:00 - 20:30	Cocktail	
Friday		
9:00 – 11:00	Regulatory HA - Strategy - General approach for labelling recommendations - Examples	Flora Musuemba (Federal Agency for Medicines and Health Products, Brussels, Belgium. University of Namur, Namur, Belgium)
11:00 - 11:30	Coffee break	
11:30 - 13:00	Biologic DDI - Review of guidelines - Case example	Hélène Guillemin/ Florian Simon (sanofi)

^{*} Including a coffee break

Number of participants

- 20 students registered in one of the 4 Master 2 co-organizing this workshop
- 15 industrial/academic delegates

Registration fees (including lunch, coffee breaks and cocktail)

- Student rate: free registration, 10 euros for membership (mandatory)
- Industrial/academic rate:
 - Early bird (before GMP symposium from 15th -17th October 2025):
 550€ + 50€ for non-members of GMP or AFPT.
 - o **After GMP symposium: 650**€ + 50€ for non-members of GMP or AFPT





Location

SANOFI

371 rue du professeur Blayac

34080 Montpellier (France)

https://maps.google.com/maps?hl=fr&gl=fr&um=1&ie=UTF-8&fb=1&sa=X&ftid=0x12b6ae9c8a0c0a7f:0xddbfe1466777c328

Requirements

Delegates are required to bring a laptop computer