



3rd EUROPEAN COURSE ON PHARMACOKINETICS AND PHARMACODYNAMICS OF PROTEIN THERAPEUTICS

PRINCIPLES AND PHARMACOMETRIC APPROACHES

LYON, FRANCE, 28-30 NOVEMBER 2018

COURSE DIRECTORS

Bernd Meibohm, University of Tennessee, and Johan Gabrielsson, Swedish University of Agricultural Sciences

ORGANIZER AND REGISTRATION SUPPORT

AP2POP, Lyon, France

LOCAL HOSTS

Emilie Hénin, Christian Laveille (Calvagone)

This 3-day course will introduce participants to basic principles in the pharmacokinetics and pharmacodynamics of novel therapeutic proteins and provide opportunities for basic hands-on exercises in the PK/PD evaluation of these compounds. Topics include target-mediated drug disposition, tissue and tumor penetration, first-in-human dose selection, immunogenicity, clinical pharmacology challenges, biosimilars, and drug-drug interactions.

The course is a shortened version of the week-long course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation' that Profs Meibohm and Gabrielsson have offered for the last eight years in the United States. Hands-on exercises and simulations will be performed individually and in small groups using simple software tools (no prior experience required).

Further information on that course can be found at www.PKPDofProteinTherapeutics.com

COURSE LOGISTICS

COURSE VENUE

Campanile Hotel, 31 rue Maurice Flandin, 69003 Lyon, France

REGISTRATION FEE

Regular: **€1800** Academia/Trainee: **€600**

Registration fee includes access to all course sessions, course material in electronic form, lunch and coffee breaks, and a joint dinner. Reservations will only be acknowledged and participation in the course guaranteed after receipt of both the registration form AND the registration fee. The number of course participants will be limited to 35. The number of slots for academic participants and trainees will also be limited.

PAYMENT INFORMATION

- Preferred option is by electronic transfer to AP2POP bank account:
IBAN: FR76 1450 6000 2272 8319 7386 383, BIC: AGRIFRPP845
indicating "PKPD Protein course" and the participant's name.
- Alternatively, payment can be made by Credit Card via PayPal (ask contact@ap2pop.org)

ACCOMMODATION

Campanile hotel is the easiest way to book a room (<https://www.campanile.com/fr/hotels/campanile-lyon-centre-gare-part-dieu>). No arrangements have been made with Campanile hotel.

Alternatively, participants have access to wide offer of hotels in Lyon at walking distance or easily accessible by local transportation through the usual booking sites. Participants have to make their own hotel arrangements.

TRAVEL INFORMATION

Lyon is easily accessible by plane from many European cities followed by 30 minutes direct train from the airport, or 40 minutes taxi. Campanile hotel is 2 min walk away from the terminus of direct Rhônexpress shuttle from and to airport.

Alternatively, Part-Dieu train station is 5 min walk from the Campanile Hotel.

CANCELLATION POLICY

If cancelled more than 30 days before the course starts, enrolled participants will be subject to a €600 (€200) registration fee for Industry (Academic). There will be no refund of fees if registration is canceled 30 days or less before the course begins. Substitution of enrolled course participants with another person from the same organization is acceptable.

INFORMATION FROM AP2POP COURSE ORGANIZER:

Email contact@ap2pop.org

Web <http://www.ap2pop.org/formations>

COURSE SCHEDULE

TIME	Wednesday 28 November	Thursday 29 November	Friday 30 November
TOPIC	Basic Concepts	PK/PD	Developmental Aspects
8:15-9:00		How to establish the steady-state relationship of ligand, target and complex? TMDD2	Regulatory and Clinical Pharmacology Challenges for Biologics Development
9:00-9:45		First-in-Human Dose predictions	Disease state effects and covariates modulation the PKPD of therapeutic proteins
Break			
10:00-10:45	Basic Pharmacokinetics of Proteins & Peptides – Part 1		
10:00-10:45	Basic Pharmacokinetics of Proteins & Peptides – Part 1	PKPD Modeling & Simulation: Concepts of Rapid Equilibrium and Distribution	Evaluation of Drug-Drug Interactions for Biologics
10:45-11:30	Basic Pharmacokinetics of Proteins & Peptides – Part 2	PKPD Modeling & Simulation: Concepts of turnover models	Group Exercises: PKPD Modeling
11:45-12:30	Basic Concepts of Target-Mediated Drug Disposition TMDD1	PKPD Modeling & Simulation: Complex turnover model	Group Exercises: PKPD Modeling
Lunch			
1:30-2:15	Hands-on Maxsim2 Lab I	Hands-on Maxsim2 Lab III	Immunogenicity: Impact on PK and PD
2:15-3:00	Hands-on Maxsim2 Lab I	Hands-on Maxsim2 Lab III	New Scaffolds: Bispecifics and Antibody-Drug Conjugates
Break			
3:15-4:00	Hands-on Maxsim2 Lab II	Pattern Recognition Exercises	Biosimilars, and Wrap-up Day 3
4:00-4:45	Tissue Distribution and Tumor Penetration	Pattern Recognition Exercises	
4:45-5:00	Wrap-up Day 1	Wrap-up Day 2	

The schedule may be subject to minor changes.



REGISTRATION FORM

3rd European Course on Pharmacokinetics and Pharmacodynamics of Protein Therapeutics
- Principles and Pharmacometric Approaches -
November 28-30, 2018 Lyon (France)

Firstname :	Lastname:
Degree:	Title:
Organization:	Business Address:
City:	ZIP:
Country:	Business Phone:
Email Address:	Dietary Restrictions : <input type="checkbox"/> Vegetarian <input type="checkbox"/> Other:

REGISTRATION FEE FOR COURSE SESSIONS, COURSE MATERIAL, LUNCH & COFFEE BREAKS (CHECK APPROPRIATE):

- | | |
|--|---|
| <input type="checkbox"/> Industry | 1,800 EURO (+€25 by Credit Card) |
| <input type="checkbox"/> Academic / Student (documentation of status required) | 600 EURO (+€10 by Credit Card) |

PAYMENT BY (CHECK APPROPRIATE):

- ☐ Electronic transfer: IBAN: FR76 1450 6000 2272 8319 7386 383, BIC: AGRIFRPP845 indicating **“PKPD Protein Course”** and **the participant’s name**.
- ☐ VISA / Master Card (<http://www.ap2pop.org/formations>)

Please fill out and mail this form. If you claim for academic registration (limited spots), mail a copy of your 2018 academic ID. **Reservations will only be acknowledged and participation in the course guaranteed after receipt of both the registration form AND the registration fee.**

If cancelled more than 30 days before the course starts, enrolled participants will be subject to an €600 (€200) registration fee for Industry (Academic). There will be no refund of fees if registration is canceled 30 days or less before the course begins. Substitution of another person from the same organization is acceptable.

RETURN SCANNED FORM, PAYMENT AND COPY OF ACADEMIC AFFILIATION TO:

Emilie Hénin Email contact@ap2pop.org

Information at: Web <http://www.ap2pop.org/formations>

ACCOMMODATION: The course is organized at Campanile Hotel, the hotel is near Part-Dieu train station and 2 min walk away from the terminus of direct Rhônexpress shuttle from and to airport.