



**Course Directors:**

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

**Local Hosts:**

Pascal Girard and Maïke Puetter, Merck, Christian Laveille, Calvagone

**Sponsor:** Merck

**Organizer and Registration Support:** AP<sup>2</sup>POP, Lyon, France

This second 3-day course, following the one given in Lausanne (CH) last year 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. Hands-on exercises and simulations will be performed individually and in small groups using simple software tools (no prior experience required).

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 Drs. Meibohm and Gabrielsson have offered for the last seven years in the United States. Further information on that course can be found at [www.PKPDofProteinTherapeutics.com](http://www.PKPDofProteinTherapeutics.com)

### Course Logistics

**COURSE VENUE:** Darmstadtium, Schlossgraben 1, 64283 Darmstadt, Germany <https://www.darmstadtium.de/en/>

**REGISTRATION FEE:** Regular: € 1400      Academia/Trainee: € 500 (thanks to Merck Sponsorship)

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 AP<sup>2</sup>POP bank account: BIC code: AGRIFRPP845 and IBAN: FR76 1450 6000 2272 8319 7386 383, indicating "PKPD Protein course"
- Alternatively, payment can be made by Credit Card via PayPal (ask [contact@ap2pop.org](mailto:contact@ap2pop.org) )

**ACCOMODATION:**

The closest hotel to the [Darmstadium](#) is the Welcome Hotel, just across the street <https://www.welcome-hotels.com/en/welcomehotel-darmstadt/info/> . No arrangements have been made with the hotel.

Alternatively, participants have access to wide offer of hotels in Darmstadt at walking distance or easily accessible by [tramway](#) through the usual booking sites. Participants have to make their own arrangement and book their hotel themselves.

**TRAVEL INFORMATION:**

Darmstadt is easily accessible by plane from Frankfurt International airport followed by 30 minutes direct train from the airport, or 40 minutes taxi.

**CANCELLATION POLICY:**

If cancelled more than 30 days before the course starts, enrolled participants will be subject to a € 600 registration fee. 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:**

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

Email: [contact@ap2pop.org](mailto:contact@ap2pop.org)

## Course Schedule

Time	Tuesday, August 29	Wednesday, August 30	Thursday, August 31
<b>Topic</b>	<b>Basic Concepts</b>	<b>PK/PD</b>	<b>Developmental Aspects</b>
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
	<i>Break</i>	<i>Break</i>	<i>Break</i>
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
	<i>Lunch</i>	<i>Lunch</i>	<i>Lunch</i>
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
	<i>Break</i>	<i>Break</i>	<i>Break</i>
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:

2<sup>nd</sup> European Course on Pharmacokinetics and  
Pharmacodynamics of Protein Therapeutics  
- Principles and Pharmacometric Approaches -  
August 29-31, 2017 Darmstadt (Germany)

Sponsored by [Merck](#)

Name: \_\_\_\_\_  
First Last

Degree: \_\_\_\_\_

Dietary restrictions:

Title: \_\_\_\_\_

Vegetarian  Other \_\_\_\_\_

Organization: \_\_\_\_\_

Business address: \_\_\_\_\_

City: \_\_\_\_\_ ZIP \_\_\_\_\_ Country \_\_\_\_\_

Business Phone: (\_\_\_\_) \_\_\_\_\_

Email Address: \_\_\_\_\_

**Registration fee for course sessions, course material, lunch, coffee breaks and 1 dinner (check appropriate):**

- Industry **1,400 EURO (+25€ by Credit Card)**  
 Academic / Student (documentation of status required) **500 EURO (+10€ by Credit Card)**

Academic pricing is sponsored by Merck and is in limited number, based on first come, first served.

**Payment by (check appropriate):**

- Electronic transfer: BIC code: AGRIFRPP845 and IBAN: FR76 1450 6000 2272 8319 7386 383, indicating  
"PKPD Protein Course"  
 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 2017 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 500 € (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:**

Christian Laveille Email [contact@ap2pop.org](mailto:contact@ap2pop.org)  
Information at: <http://www.ap2pop.org/formations>

**Accommodation:** The course is organized at the [Darmstadium](#), the congress center in downtown Darmstadt. The closest hotel is the [Welcome](#), just across the street. No arrangements have been made with the hotel. Alternatively, participants have access to wide offer of hotels in Darmstadt 10 min away by tramway.