



1st European Course on Pharmacokinetics and Pharmacodynamics of Protein Therapeutics Principles and Pharmacometric Approaches

Lausanne, Switzerland, March 21-23, 2016

Course Directors:

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

Local Hosts:

Pascal Girard, Merck Institute for Pharmacometrics, and Chantal Csajka, University Hospital of Lausanne

Sponsor: **Merck**

Organizer and Registration Support: **AP²POP**, Lyon, France

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. 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 five years in the United States. Further information on that course can be found at www.PKPDofProteinTherapeutics.com

Course Logistics

COURSE VENUE: Starling Hotel Lausanne, Route Cantonale 31, 1025 Saint-Sulpice, Switzerland (☎ +41 21 694 85 85)

REGISTRATION FEE: **Regular:** €1800 **Academia/Trainee:** €600 (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 30. The number of slots for academic participants and trainees 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, indicating "PKPD Protein course"
- Alternatively, payment can be made by Credit Card via PayPal (ask contact@ap2pop.org)

ACCOMODATION:

The course is organized at the Starling hotel in Lausanne, a comfortable modern hotel, overseeing the lake and the Alps. A limited number of rooms have been reserved in this Hotel with preferred rate, including breakfast:

- 185 CHF single occupancy,
- 215 and 245 CHF for double and triple occupancy, respectively.

For room reservation at the Starling go to <https://goo.gl/HPtpR0> and enter special corporate code **MEO7751**.

One alternative hotel at walking distance is the Swisstech Hotel (≈150 CHF/ night <http://www.swisstech-hotel.com/>).

Other hotels will be in Lausanne. Starling can easily be reached by metro (line M1, stop EPFL) or buses (lines 701, 31).

TRAVEL INFORMATION

Lausanne is easily accessible by plane from Geneva airport followed by 40 minutes direct train from the airport, by train, by car, or even by boat from Evian to Saint Sulpice. A free shuttle will be provided by the hotel from Lausanne Central Station at pre-specified hours.

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/fr/Formations.html>

Email: contact@ap2pop.org

Course Schedule

Time	Monday, March 21	Tuesday, March 22	Wednesday, March 23
Topic	Basic Concepts	PK/PD	Developmental Aspects
8:15-9:00		Disposition and Modeling of Endogenous Compounds	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
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	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 Life Cycle Management, 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:

1st European Course on Pharmacokinetics and
Pharmacodynamics of Protein Therapeutics
- Principles and Pharmacometric Approaches -
March 21-23, 2016 in Lausanne (Switzerland)

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 and 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) |

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

Payment by (check appropriate):

- ☐ Electronic transfer: IBAN: FR76 1450 6000 2272 8319 7386 383, indicating "PKPD Protein Course"
- ☐ VISA / Master Card (<http://www.ap2pop.org/fr/Formations.html>)

Please fill out and mail this form. If you claim for academic registration (limited spots), mail a copy of your 2016 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 € (300 €) 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: <http://www.ap2pop.org/fr/Formations.html>

Accommodation: The course is organized in Starling Hotel a comfortable modern hotel, overseeing the lake and the Alps. Limited number of rooms have been secured with special rate and can be found here <https://goo.gl/HPtpR0> with special corporate code MEO7751 (single 185 €, double 215 €, triple 245 €). Other hotel at walking distance is the Swistech Hotel <http://www.swistech-hotel.com/>.