

Simulations Plus presents:
The Advanced GastroPlus™ DMPK and Clinical Pharmacology Workshop



March 22 - 23, 2018 in Mainz, Germany

Simulations Plus, the industry's leading provider of simulation and modeling software for drug discovery and development, will be hosting its "Advanced GastroPlus™ DMPK and Clinical Pharmacology Workshop" in Mainz, Germany on March 22 - 23, 2018.

This 2-day hands-on course will provide an in-depth knowledge of the theories and application of state-of-the-art simulation and modeling software as it applies to problems facing DMPK and Clinical PK/PD scientists dealing with complex effects on drug absorption, pharmacokinetics, pharmacodynamics, and drug-drug interactions. A combination of presentations and interactive examples, taken from actual industry experience, will illustrate how to recognize and deal with the multiple interacting phenomena that affect the absorption, PBPK/PD, and DDIs of particular drugs, dosing routes, and dosage forms in different populations.

This is an advanced course – a prerequisite is familiarity with setting up and running basic GastroPlus simulations, including database and support file structures, basic inputs for physicochemical and formulation parameters, and basic physiology options for human and animal simulations, as these items will not be covered in this course due to time constraints. If you are not yet familiar with all of these concepts, you can gain the required familiarity in our "Introductory GastroPlus™ Simulation and Modeling Workshop" that will be held immediately preceding this workshop.



Attendance for this event is limited, so register today!



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Who should attend?

This workshop is appropriate for scientists working in preclinical and clinical pharmacokinetics and pharmacodynamics who want an in-depth understanding of how the highly interactive processes of absorption (passive and carrier-mediated), metabolism in the gut and other tissues, and whole-body distribution affect PK and PD. Although the course will use GastroPlus for all case studies, the guiding principles will be taught in a software-independent manner. Class size is limited to encourage interaction with the course instructors and among attendees. Past GastroPlus workshop attendees have commented that the interaction and networking among industry, government, and academic scientists is an important and valuable part of the experience!

What will you learn?

Upon completion of this course, you should have an understanding of the interactions that exist among the various mechanistic phenomena affecting drug absorption, pharmacokinetics (employing both compartmental PK and physiologically based pharmacokinetics - PBPK), pharmacodynamics, and DDIs. You should be able to decide when a mechanistic absorption/PBPK model is more appropriate for building your PD models. And you should be able to communicate readily with the groups that produce both preclinical and clinical data to express your data needs as well as present your results clearly back to them and to project leaders and management.

You will gain experience with:

- screening small compound libraries for absorption (transcellular & paracellular) from chemical structure and *in vitro* data.
- recognizing when to use PBPK vs. standard compartmental PK models
- predicting first-in-human doses with available preclinical and *in vitro* data (IVIVE)
- using *in vitro* data to define whole-body, permeability-limited models to simulate tissue uptake (transporter-based IVIVE)
- tracking parent and metabolite concentrations through multiple pathways, in plasma and tissues
- defining inputs to simulate prodrug/drug exposure
- assessing the potential for biliary excretion and modeling enterohepatic circulation
- building PBPK/PD models using simulated target tissue concentrations
- predicting drug-drug interactions for various situations (e.g., auto-inhibition)
- simulating populations including selected mixes of ages, gender ratios, and ethnicities
- predicting pediatric exposure from adult PBPK models
- understanding optimization methods, objective function weighting, and constraints



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How will the workshop operate?

All presentation files and data sets needed to run case studies will be available in electronic format. The University will provide computers for attendees.

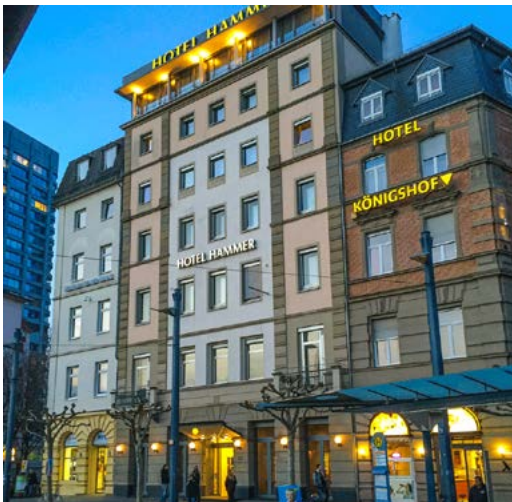
Continental breakfast, refreshment breaks, and lunch will be provided each day.

Where will this be held?



The workshop will be held at:

Johannes Gutenberg University Mainz
Building 1430 Anthropologie
Anselm-Franz-von-Bentzel-Weg 7
Room 00 101
55099 Mainz, Germany



A limited number of discounted rooms will be available for attendees of the workshop at:

The Hotel Hammer in Mainz, Germany
Bahnhofpl. 6, 55116 Mainz, Germany
Phone: +1+49 (0) 6131 96 528-0
Fax: +1+49 (0) 6131 96 528-88
www.hotel-hammer.com

REGISTRATION FORM

Attendance is limited • Please register by March 5, 2018

Please fill in this form and return to Renee Bouche (renee@simulations-plus.com); Fax: +1-661-723-5524
To register by phone, please call Renee at +1-661-723-7723 ext. 227

The Advanced GastroPlus™ DMPK and Clinical Pharmacology Workshop March 22 - 23, 2018 in Mainz, Germany

Title: Professor / Dr. / Mr. / Mrs. / Miss / Ms.

FIRST NAME: _____

LAST NAME: _____

COMPANY: _____

POSITION: _____

DEPARTMENT: _____

ADDRESS: _____

TELEPHONE: _____

EMAIL: _____

PURCHASE ORDER NO. (if applicable): _____

Cost for the workshop is USD \$1200 per person (industry) and USD \$600 (academic & government) and includes all workshop materials, continental breakfast, refreshment breaks, and lunch each day. Also, a one (1) month single-user license to GastroPlus, with all optional modules, is available after the workshop.

Hotel accommodations are not included with registration, but special room rates are available through The Hotel Hammer.

Method of payment (Please check one)

Credit card (a confirmation message will be sent to the email address provided)

Name on card: _____ Email: _____ Tel: _____

Card billing address: _____

_____ Zip/Post Code: _____

Type of card: Visa MasterCard AMEX Card Number: _____

Expires: _____ Security code: _____

Payment by check (you will be invoiced upon receipt of your completed registration form)

Payment by wire transfer (you will receive wire transfer information upon receipt of your completed registration form)

Payment online (you will be redirected to the payment portal when registering online at simulations-plus.com/workshops)

Terms and Conditions

Cancellation Policy: Cancellations made prior to March 5, 2018 will be eligible for an 80% refund. Refunds for cancellations will be honored up to 45 days after the date of payment for credit card transactions. Substitutions are allowed up to 10 days before the event.

Payment Terms: Following completion and return of the registration form, the total fee must be paid within 30 days of receipt of invoice. All fees must be paid in full prior to the start of the workshop.



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