

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



*October 13-14, 2016 at the Hyatt Regency Bethesda
in Bethesda, Maryland*

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 Bethesda, Maryland, October 13-14, 2016.

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 Pharmacology 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. 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 October 10-12, 2016 immediately preceding this workshop.



Attendance for this event is limited, so register today!

Who should attend?

This workshop is appropriate for scientists working in DMPK and clinical pharmacology 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
- understanding optimization methods, objective function weighting, and constraints

How will the workshop operate?

All presentation slides will be available in hard-copy format. Attendees will be responsible for bringing their own laptop computers, with GastroPlus installed prior to the course.

Refreshment breaks and lunch will be provided each day.

When and where will this be held?

The workshop will be held October 13-14, 2016 at:



Hyatt Regency Bethesda
One Bethesda Metro Center
(7400 Wisconsin Avenue)
Bethesda, MD 20814
+1-301-657-1234

REGISTRATION FORM

Attendance is limited • Please register by October 1, 2016

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 GastroPlus™ Advanced DMPK/Clinical Pharmacology Workshop • October 13-14, 2016

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 \$1,200 per person (industry) and USD \$600 (academic) 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, will be available after the workshop.

Hotel accommodations are not included with registration, but special room rates are available through the Hyatt Regency.

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)

Terms and Conditions

Cancellation Policy: Cancellations made prior to October 1, 2016 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 or prior to the start of the workshop (whichever is earlier).