

*Simulations Plus presents:
The Introductory GastroPlus™ Simulation and Modeling Workshop*



*October 10-12, 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 an "Introductory GastroPlus™ Simulation and Modeling Workshop" in Bethesda, Maryland, October 10-12, 2016.

This three-day, hands-on course provides a working knowledge of the basic theories and application of state-of-the-art PBPK simulation and modeling software for the analysis of drug dissolution and absorption, coupled with the resulting pharmacokinetics and pharmacodynamics. A combination of presentations and interactive examples, taken from actual industry experience and using GastroPlus, illustrate how to recognize and deal with the multiple interacting phenomena that affect the absorption, PBPK/PD and DDIs of particular drugs and dosage forms.



Attendance for this event is limited, so register today!

Who should attend?

This workshop is appropriate for pharmaceutical/biotechnology scientists and engineers in the areas of DMPK, ADME, preformulation/formulation development, biopharmaceutics, pharmacokinetics, and clinical pharmacology. This is a beginner's course - prior experience with GastroPlus is not required. The course will use GastroPlus for all case studies, but 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. 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 a solid 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 will understand and learn to recognize potential interactions among such factors as:

- pKa – ionization effects on dissolution, absorption and distribution
- solubility and permeability changes in the various environments in the gastrointestinal tract
- differences in physiology between human and preclinical species
- potential for drug degradation in the lumen
- formulation effects, including particle size distributions and controlled release dosage forms
- effects of food/mealtimes on physiology and on the drug
- influx and efflux transporters in the gut wall and in other tissues
- metabolizing enzymes in the gut wall and in other tissues
- renal clearance and its variables

You will gain basic experience with:

- predicting drug properties from chemical structures using the ADMET Predictor™ Module
- recognizing when to use PBPK vs. standard compartmental PK models
- predicting first-in-human doses with available preclinical and *in vitro* data
- assessing formulation strategies such as micronization and nanoparticles
- fitting nonlinear metabolism and transport models
- estimating steady-state and dynamic DDIs
- building PBPK/PD models using simulated target tissue concentrations
- simulating populations including selected mixes of ages, gender ratios, and ethnicities
- running virtual crossover trials to predict bioequivalence
- deconvoluting *in vivo* dissolution to generate more useful IVIVCs
- modeling the *in vivo* exposure of large molecules (biologics)
- 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 10-12, 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 Introductory GastroPlus™ Simulation and Modeling Workshop • October 10-12, 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 \$1200 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, is 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).