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



September 11 - 13, 2017 in Cambridge, Massachusetts

Simulations Plus, the industry's leading provider of simulation and modeling software for drug discovery and development, will be hosting its "Introductory GastroPlus™ Simulation and Modeling Workshop" in Cambridge, Massachusetts on September 11 - 13, 2017.

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 solubility, dissolution, permeability and absorption
- 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<sup>TM</sup> 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 files and data sets needed to run case studies will be available in electronic format. All attendees will be responsible for bringing their own laptop computers.

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

# Where will this be held?





### **Hyatt Regency Cambridge** 575 Memorial Drive

Cambridge, MA 02139 Phone: (617) 492-1234

www.cambridge.regency.hyatt.com

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 September 11 - 13, 2017 in Cambridge, Massachusetts

Title: Professor / Dr. / Mr. / Mrs. / Mis	ss / Ms.	
FIRST NAME:		
LAST NAME:	COMPANY:	
POSITION:	DEPARTMENT:	
ADDRESS:		
TELEPHONE:	EMAIL:	
PURCHASE ORDER NO. (if applicable):		
Cost for the workshop is USD \$1200 per per- continental breakfast, refreshment breaks, an optional modules, is available after the worksh Hotel accommodations are not included with r	d lunch each day. Also, a one (1) monthop.	single-user license to GastroPlus with all
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 upor	n receipt of your completed registration	form)
Payment by wire transfer (you will receive	wire transfer information upon receipt o	of your completed registration form)
Terms and Conditions Cancellation Policy: Cancellations made prior to August 45 days after the date of payment for credit card trail Payment Terms: Following completion and return of the state of the	nsactions. Substitutions are allowed up to 10	days before the event.