Simulations Plus presents: <u>The GastroPlus™ PBPK Modeling &</u> Simulation Workshop



December 12-13, 2017 at the University of Maryland School of Pharmacy in Baltimore

Simulations Plus, the industry's leading provider of simulation and modeling software for drug discovery and development, will be hosting its "GastroPlus™ PBPK Modeling & Simulation Workshop" at the University of Maryland School of Pharmacy in Baltimore on December 12 - 13, 2017.

This two-day, hands-on course provides a working knowledge of the theories and application of our state-ofthe-art PBPK modeling and simulation software for the analysis of drug dissolution and absorption, coupled with the resulting pharmacokinetics, pharmacodynamics, and drug-drug interactions (DDIs). 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 drugs as they progress to the clinic.



Science+software=success 42505 10th Street West • Lancaster, CA 93534 • USA • phone: +1-661-723-7723 fax: +1-661-723-5524 • email: info@simulations-plus.com • www.simulations-plus.com • NASDAQ: SLP

Who should attend?

This workshop is appropriate for research scientists and engineers in the areas of DMPK, ADME, biopharmaceutics, and clinical pharmacology. 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 dissolution, 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, precipitation, absorption, and distribution
- solubility and permeability changes in the various environments in the gastrointestinal tract
- differences in physiology between human and preclinical species
- transit times through various gut regions and how and why they may vary
- formulation effects, including particle size distributions and controlled release dosage forms
- 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 experience with:

- screening compound libraries for absorption and bioavailability using chemical structures
- 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
- understanding and identifying DDI risk
- simulating populations including selected mixes of ages, gender ratios, and ethnicities
- estimating local concentration of drug following dermal administration
- understanding optimization methods, objective function weighting, and constraints
- building mechanistic IVIVCs to assess product performance and predict virtual bioequivalence

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, with GastroPlus™ installed prior to the course.

Lunch will be provided.

Where will this be held?



The workshop will be held December 12 - 13, 2017 at the University of Maryland School of Pharmacy:

20 N. Pine Street Baltimore, MD 21201

Click the following links to learn more: Driving Directions Campus Map Parking Garages Visitor Parking

If you are traveling from out of town, the University of Maryland School of Pharmacy suggests making accommodations at one of the hotels listed below. Please request the "University of Maryland Preferred Rate" when making your reservation.

Hampton Inn Baltimore Downtown Convention Center

550 Washington Blvd. Baltimore, MD 21230 Phone: (410) 685-5000

Holiday Inn - Inner Harbor 301 W. Lombard Street Baltimore, MD 21201 Phone: (410) 685-3500





REGISTRATION FORM

Attendance is limited • Please register by November 28, 2017

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[™] PBPK Modeling & Simulation Workshop December 12-13, 2017 at the University of Maryland School of Pharmacy

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 \$500 per person for anyone who is not affiliated with the University of Maryland. Price includes all workshop materials 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 accommodation is not included with registration.	
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: Security code:	
Payment by check (you will be invoiced upon receipt of your of	
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 upon receipt of your completed registration form)	
Terms and Conditions Cancellation Policy: Cancellations made prior to November 28, 2017 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.

