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



September 14-15, 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 "Advanced GastroPlus™ DMPK and Clinical Pharmacology Workshop" in Cambridge, Massachusetts on September 14 - 15, 2017.

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!

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 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

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



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REGISTRATION FORM

Attendance is limited • Please register by August 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 Advanced GastroPlus[™] DMPK and Clinical Pharmacology Workshop September 14 - 15, 2017 in Cambridge, Massachusetts

Title: Professor / Dr. / Mr. / Mrs. / N	/liss / 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, a optional modules, is available after the works Hotel accommodations are not included with	and lunch each day. Also, a one (1) month shop. h registration, but special room rates are	n single-user license to GastroPlus with all
Method of payment (Please check one		
Credit card (a confirmation message will b	. ,	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 up	on receipt of your completed registration f	form)
Payment by wire transfer (you will receiv	e wire transfer information upon receipt o	f your completed registration form)
Terms and Conditions Cancellation Policy: Cancellations made prior to Augu 45 days after the date of payment for credit card to Payment Terms: Following completion and return or must be paid in full prior to the start of the worksho	ransactions. Substitutions are allowed up to 10 f the registration form, the total fee must be pai	days before the event.

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