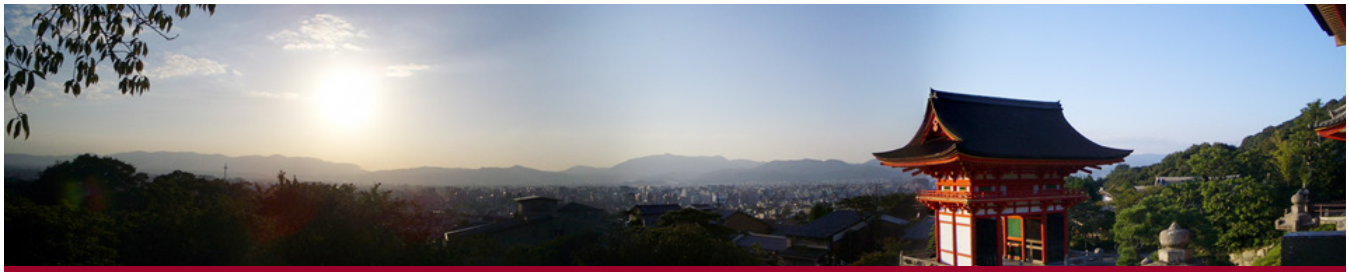
Simulations Plus presents:
The Advanced GastroPlus™ Workshop for Pharmaceutical Development

December 8-9, 2016 in Tokyo, Japan

Simulations Plus, the industry's leading provider of simulation and modeling software for drug discovery and development, will be hosting its "Advanced GastroPlus™ Workshop for Pharmaceutical Development" in Tokyo, Japan, December 8-9, 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 pharmaceutical scientists dealing with drug product effects on dissolution, absorption and pharmacokinetics. Focus will be placed on applications of this technology as it relates to issues defined in the FDA's Critical Path Initiative. 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 dissolution, absorption and pharmacokinetics of particular drugs, dosing routes, and dosage forms.

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 pharmacokinetic 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 December 5-7, 2016 immediately preceding this workshop.



Attendance for this event is limited, so register today!

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Who should attend?

This workshop is appropriate for scientists and engineers working in pharmaceutical development who need an in-depth understanding of how formulation affects the highly interactive processes of dissolution, precipitation, gastrointestinal transit, absorption (passive and carrier-mediated), first-pass metabolism and pharmacokinetics. 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 a solid understanding of the interactions that exist among the various mechanistic phenomena affecting drug dissolution, absorption and pharmacokinetics (employing both compartmental PK and physiologically based pharmacokinetics - PBPK) and how they relate to the development of drug products, both in preclinical and clinical settings.

You will gain experience with:

- incorporating modeling & simulation to assist with Quality by Design (QbD) implementation
- assessing formulation strategies (e.g., micronization and nanoparticles) earlier in product development
- analyzing the impact of common ion effect on solubility & dissolution
- screening for different salts and understanding the effect on precipitation kinetics
- properly using *in vitro* dissolution data to predict plasma concentration levels
- designing controlled release products to reach therapeutic "windows" or target concentration profiles
- deconvoluting *in vivo* dissolution to help design *in vitro* experiments and generate mechanistic IVIVCs
- identifying food effect, both positive and negative, on absorption
- running virtual bioequivalence studies to estimate sample sizes and achieve adequate power
- understanding optimization methods, objective function weighting, and constraints

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How will the workshop operate?

All presentation files and data sets needed to run case studies will be available in electronic format.

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

When and where will this be held?

The workshop will be held December 8-9, 2016 in Toyko, Japan.

REGISTRATION FORM

Attendance is limited • Please register by November 21, 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 Advanced GastroPlus™ Workshop for Pharmaceutical Development • December 8-9, 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 110,000 yen per person 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 provided after the workshop.

Hotel accommodations are 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: _____

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 November 21, 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. All fees must be paid in full prior to the start of the workshop

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