GastroPlus®

Virtual Introductory Workshop

September 26th - 30th, 2022

Workshop Overview

This introductory GastroPlus® workshop is designed to provide participants with the necessary information and skills needed to execute basic physiologically based pharmacokinetic (PBPK) modeling and simulations, and to provide a foundational understanding of the GastroPlus software.

The workshop will consist of a combination of live lectures and hands-on exercises utlizing the software.

The workshop materials are structured to demonstrate both theoretical and practical aspects of PBPK modeling yet remain versatile enough to benefit participants with diverse backgrounds.

No prior experience with GastroPlus is required. However, if you are brand new to the software, we recommend attending one of our complimentary, monthly 5-hour introductory sessions first, if possible.

Learning Objectives

At workshop completion you will have an understanding of the inputs and interactions that exist among the various mechanistic phenomena affecting drug dissolution, drug absorption, pharmacokinetics, and pharmacodynamics.

Topics will include but are not limited to the following:

- pKa – ionization effects on solubility, dissolution, permeability, and absorption
- Solubility and permeability changes in the gastrointestinal tract and the differences in physiology between humans and preclinical species
- Formulation effects including particle size distributions and controlled release dosage forms
- Predicting drug properties from chemical structures using the ADMET Predictor® Module
- Recognizing when to use PBPK versus standard compartmental PK models
- Assessing formulation strategies such as micro ionization and nanoparticles
- Fitting nonlinear metabolism and transport models
- Building PBPK-PD models using simulated target tissue concentrations
- Simulating populations such as mixes of ages, gender ratios, and ethnicities to help virtual trials predict bioequivalence
- Deconvoluting *in vivo* dissolution to generate more useful IVIVCs
- Modeling the *in vivo* exposure of large molecules (biologics)

Register online! simulations-plus.com/register-training-workshop

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Course Instruction

The workshop will be taught by experienced PBPK modelers from Simulations Plus.

Agenda (all times are Pacific Standard Time)

Monday

08:00 - 10:00 Introduction
10:00 - 10:30 **Break (30-min)**
10:30 - 14:00 Solubility Dissolution and Precipitation (**includes 30-minute break**)

Tuesday

08:00 - 09:15 Passive Permeability and Absorption
09:15 - 09:30 **Break (15-min)**
09:30 - 12:45 PBPK Modeling (IVIVE) (**includes 15-minute break**)

Wednesday

08:00 - 10:00 Nonlinear Metabolism and Carrier Mediated Transport
10:00 - 10:15 **Break (15-min)**
10:15 - 11:30 Compartmental PK Modeling
11:30 - 12:00 **Break (30-min for lunch)**
12:00 - 13:15 PBPK Modeling of Biologics

Thursday

08:00 - 11:30 Mechanistic IVIVCs and Virtual Bioequivalence Trials (**includes 30-minute break**)
11:30 - 12:00 **Break (30-min)**
12:00 - 13:15 PK-PD Modeling

Friday

08:00 - 10:00 DDI Predictions
10:00 - 10:30 **Break (30-min)**
10:30 - 12:30 Additional Dosage Routes (2 of the following: dermal, pulmonary, ocular, and intra-articular)

Virtual Platform

Training sessions will consist of live instruction and hands-on examples via Zoom Video Conference. Participants will attend virtually using their own PCs. Use of cameras and microphones are optional but encouraged.

Participants will be provided with personal access to the Simulations Plus virtual learning environment. The learning environment will contain GastroPlus software and access to downloadable course materials and example files. The learning environment will remain open to participants for one week post workshop completion. Upon workshop completion, participants may request a complimentary trial GastroPlus license for further engagement and evaluation by reaching out to **https://www.simulations-plus.com/software-evaluation-request-form/.**

Requirements

PCs equipped with internet access and Google Chrome with Flash 9+ plugins are required to participate.

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REGISTRATION FORM

Attendance is limited • Please register soon.

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September 26th - 30th, 2022 – Register by September 9th

Title: ☐ Professor ☐ Dr. ☐ Mr. ☐ Mrs. ☐ Miss ☐ Ms.

☐ Industry
☐ Academia

First name:

Last name: Company:

Job Title: Department:

Address:

Telephone: Email:

Purchase Order No. (if applicable):

Industry: $2,000
Academia: $1,000*

*You must register with a valid .edu email address

Method of payment (Please select one)

☐ **Payment by invoice** (you will be invoiced upon receipt of your completed registration form)

☐ **Payment online** (you will be redirected to the payment portal when registering online at simulations-plus.com/register-training-workshop)

Terms and Conditions

Registration: The course is limited to 25 participants. A registration confirmation email will be issued upon successful registration at the following web site: **simulations-plus.com/register-training-workshop**

Cancellations: Cancellations with a refund minus 4% credit card fees may be made two weeks prior to course start date. No refunds will be given for cancellations received after the start date. Substitutions may be made at any time.

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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