

Virtual Introductory Workshop

May 9th - 13th, 2022

Workshop Overview

This introductory <u>GastroPlus®</u> 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.

This workshop will consist of a combination of live lectures and hands-on exercises within 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 <u>complimentary, monthly 5-hour introductory sessions</u> 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 <u>ADMET Predictor® Module</u>
- 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)





Course Instruction

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

Agenda (all times are Eastern Standard Time)

<u>Monday</u>

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

Wednesday

08:00 - 10:00Nonlinear Metabolism and Carrier Mediated Transport10:00 - 10:15Break (15 min)10:15 - 11:15Compartmental PK Modeling11:15 - 12:00Break (45 min for lunch)12:00 - 13:00PBPK Modeling of Biologics

<u>Thursday</u>

- 08:00 11:30 Mechanistic IVIVCs and Virtual Bioequivalence Trials (includes 30-minute break)
- 11:30 12:00 Break (30 min)
- 12:00 13:00 PBPK-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 Microsoft Teams meetings. Participants will virtually attend using their PCs with enabling of cameras and microphones optional but encouraged.

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 SimulationsPlus 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. Access to, at a minimum, the basic GastroPlus module is also required.



GastroPlus Virtual Introductory Workshop

May 9th - 13th, 2022 - Register by May 2nd

Title:	Professor	Dr.	Mr.	Mrs.	Miss	Ms.	Industry Academia
First na	me:						
Last name:					С	company:	
Job Title:					D	epartment:	
Address:							
Telephone:					E	mail:	
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: <u>simulations-plus.com/register-training-workshop</u>

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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