

# Virtual Introductory Workshop

March 7th - 11th, 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 virtual 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)

#### **Monday**

08:00 - 10:00Introduction to GastroPlus10:00 - 10:15Break (15 min)10:15 - 13:45Solubility Dissolution and Precipitation (includes 30 minute break)

#### Tuesday

08:00 - 09:00Passive Permeability and Absorption09:00 - 09:15Break (15 min)09:15 - 12:45PBPK Modeling (IVIVE) (includes 30 minute break)

#### **Wednesday**

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

#### Thursday

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

#### **Friday**

08:00 - 10:00 DDI Predictions
10:00 - 10:30 Break (30 min)
10:30 - 12:30 Additional Dosage Routes (two 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.

## Requirements

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



## **Denise Morris**



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### GastroPlus Virtual Introductory Workshop

March 7th-11th, 2022 – Register by February 28th

Title:	Professor	Dr.	Mr.	Mrs.	Miss	Ms.	Industry Academia	
First na	me:							
Last na	me:				С	ompany:		
Job Titl	e:				D	epartment:		
Address	5:							
Telepho	one:				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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