

### **Workshop Overview**

This advanced <u>GastroPlus®</u> workshop will build upon the introductory workshop by providing an in-depth exploration of PBPK theory, execution, and application of the software.

To attend this workshop participants should be familiar with the following.

- Running basic GastroPlus simulations
- Database and support file structure
- Primary inputs for physiochemical and pharmacokinetic parameters
- · Basic physiology options for human and animal simuations

If you are new to GastroPlus we highly recommend attending one of our complimentary, monthly introductory training sessions or one of our paid introductory workshops prior to attending an advanced workshop.

This workshop will consists of a combination of live lectures and hands-on excercises using the software. The materials are selected to demonstrate both the theoretical and practical aspects of PBPK modeling.

This workshop is geared towards scientists 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.

#### **Learning Objectives**

At workshop completion, you will have an understanding of the following:

#### Topics will include but are not limited to the following:

- Incorporating modeling and simulation to assist with Quality by Design (QbD) implementation
- Assessing formulation strategies (e.g., microionization and nanoparticles) earlier in product development
- Analyzing the impact of common ion effect on solubility and dissolution
- Predicting drug properties from chemical structures using the ADMET Predictor® Module
- Recognizing when to use PBPK versus standard compartmental PK models







#### **Course Instruction**

The workshop is taught by experienced PBPK modelers from Simulations Plus.

# Agenda (all times are Pacific Standard Time)

### **Monday**

08:00 - 12:30 Course Intro., Common Ion Effect on Solubility, Dissolution, and Precipitation Kinetics (includes 30-minute break)

#### **Tuesday**

08:00 - 10:00 Salt Selection/Screening and the Impact on Precipitation Kinetics 10:00 - 10:30 Break (30 min)

10:30 - 12:30 In Vitro Dissolution and Z-Factor Model

#### **Wednesday**

08:00 - 10:00 **Food Effect** 10:00 - 10:30 Break (30 min)

10:30 - 12:30 Formulation Optimization

#### **Thursday**

08:00 - 10:00 IVIVC and Integration with DDDPlus

10:00 - 10:30 Break (30 min)

10:30 - 12:30 Virtual Bioequivalence Trials

# **Virtual Platform**

Training sessions will consist of live instruction and hands-on examples and will be offered via Microsoft Teams meetings. Participants will virtually attend using their own 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** 

Industry

## **GastroPlus Virtual Advanced Workshop:**

Pharmaceutical Development

January 24th-27th, 2022 - Register by January 17th

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



