

Workshop Overview

This advanced <u>GastroPlus®</u> workshop will provide a more in-depth exploration of PBPK theory, execution, and application of the software as compared to the introductory workshop.

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

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

The workshop will consist of a combination of live lectures and hands-on exercises within the software. The materials are selected to demonstrate both the theoretical and practical aspects of the PBPK modeling.

If you are new to GastroPlus we recommend attending one of our <u>complimentary, monthly introductory training sessions</u> or ideally one of our <u>paid introductory workshops</u> **prior** to attending the advanced workshop.

Learning Objectives

At workshop completion you will have an understanding of 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 vs. standard compartmental PK models

The goal is to provide you with the tools you need to communicate data needs to your operational groups producing preclinical and clinical data, and to clearly present your results to project leaders and management.







Course Instruction

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

Agenda (All times are Eastern)

Monday (July 25th)

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

Tuesday (July 26th)

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 (July 27th)

08:00 - 12:00 Food Effect

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

10:30 - 12:30 Formulation Optimization

Thursday (July 28th)

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 guided, hands-on examples via the Microsoft Teams meeting platform.

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.



Industry

GastroPlus Virtual Workshop: Advanced Pharmaceutical Development

July 25th - 28th, 2022

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 check one)							
Payment by check (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. An email confirming registration will be issued within 2 busines days upon receipt of registration.

Cancellations: Cancellations with a refund minus 4% credit card fees may be made two weeks before course date. No refunds will be given for cancellations received after this 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.







