GastroPlus®

Physiologically Based Pharmacokinetic Modeling for FIH Predictions Virtual Workshop

February 21st - March 18th, 2022

Workshop Overview

Physiologically based pharmacokinetic modeling is routinely used during drug discovery for *in-vitro* to *in-vivo* translation and pharmacokinetic modeling in preclinical species. This can lead to the application of verified PBPK models for first-in-human (FIH) pharmacokinetic predictions. This FIH-focused GastroPlus workshop will provide an in-depth exploration of PBPK theory, execution, and application of the software as it pertains to FIH predictions.

Pre-requisite: Completion of a GastroPlus® Introductory Workshop within the past 3 years – OR – confirmation that participant is proficient in the following:

- Database and support file structure
- Understanding and implementing inputs for physicochemical and pharmacokinetic parameters
- Running GastroPlus® simulations
- Understanding and implementing physiology options for human and animal simulations (ACAT and PBPK)
- General concepts with respect to:
    - Processes that govern absorption
    - Processes that govern distribution and elimination of compounds (including metabolism and / or transporter effects)

This workshop will run over 4 weeks as a combination of on demand content, live virtual sessions, hands-on applications, and implementation of concepts in a "real world" exercise.

Learning Objectives

At workshop completion, you will have an understanding of how to predict first-in-human pharmacokinetics using PBPK with available preclinical and *in vitro* data.

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 clearly present your results to project leaders and management.

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

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Instructor

This workshop will be taught be **Neil Miller** (Vice President, Simulation Sciences)

Neil Miller

Agenda

Week 1 (February 21st to February 25th)
On demand lectures available for viewing. Please note that lectures will be available for viewing during the entire length of the workshop.

Week 2 (February 28th to March 4th)
Participants can select from one of two, 2-hour live virtual sessions that will cover hands-on exercises and Q&A.
- Tuesday, March 1st, 3-5 pm (London) / 10am-12 pm (New York) / 7-9 am (Los Angeles)
- Wednesday, March 2nd, 6-8 pm (London) / 1-3 pm (New York) 10am-12 pm (Los Angeles)

Week 3 and Week 4 (March 7th to March 18th)
FIH Prediction Project – Participants will have the opportunity to work on an assigned project. During this time, participants will have access to select office hours to ask questions and troubleshoot as they work through the project. Assignments will be graded, and a Certificate of Completion provided to participants approximately 2 weeks after the project deadline of March 18th.

Virtual Platform

Training sessions will consist of on demand content, live instruction, and the following hands-on examples:

- Gabapentin and evaluation of input parameters for Kp calculations
- Tobramycin and an appropriate tissue model
- Ranitidine and the translation from dog to human

Participants will virtually attend using their PCs with enabling of cameras and microphones *optional but encouraged*.

Technical Requirements

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

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GastroPlus Virtual Introductory Workshop

February 21st - March 18th, 2022

Registration opens November 30th, 2021 and closes February 7th, 2022

Industry
Academia

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

First name:

Last name: Company:

Job Title: Department:

Address:

Telephone: Email:

Purchase Order No. (if applicable):

Maximum of 25 people for this workshop

Industry: $2,000
Academia: $1,000* (Two Academic Slots Available)

*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 before 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.