AN INTRODUCTORY WORKSHOP IN PHARMACOMETRICS USING MONOLIXSUITE®

SimulationsPlus

3-DAY INTERACTIVE COURSE
Thursday, May 14 – Saturday, May 16, 2026
Niagara Falls, NY

University at Buffalo
School of Pharmacy and Pharmaceutical Sciences

WORKSHOP SYNOPSIS

This three-day interactive workshop will guide you through the **essentials of population PK/PD modeling** while building the practical skills needed to apply these methods in research and development. By the end, you will be able to build, refine, and simulate models with confidence using **MonolixSuite®**.

The program is tailored for a broad audience:

- **Students and beginners** who are just starting with pharmacometrics and want a solid introduction.
- **Intermediate modelers** seeking to strengthen their approach to model development and simulations.
- **Experienced users** aiming to streamline workflows, run efficient simulations, and adopt best practices for reproducibility and regulatory submissions.

Through a balanced **mix of lectures, hands-on practice, and discussions**, the workshop builds both understanding and applied expertise. Realistic case studies guide participants through complete workflows — from data exploration and model development to simulations of dosing regimens and clinical trials. Exercises mirror the day-to-day work of a modeller, integrating customization, reproducibility, and automation, while providing guidelines to accelerate workflows and comply with FDA and EMA standards.

No prior experience with MonolixSuite® is required.
A temporary MonolixSuite® license is provided to all participants to continue practicing after the workshop.

LEARNING OBJECTIVES

Following this workshop, participants will:

- **Gain a solid background** in the population modeling approach with nonlinear mixed-effects (NLME) models, understanding when and why to use them, with foundational knowledge in PK and PD modeling.
- **Learn the importance of data exploration** for successful model development, including data formatting, visualization, and diagnostic tools for identifying trends, variability, and potential covariates.
- **Develop skills in model building**, from defining structural and statistical models to stepwise covariate analysis, model comparison, and refinement strategies.
- **Understand technical aspects of model selection and evaluation**, using diagnostic plots, statistical criteria, and algorithm settings to assess model performance and reliability.
- **Acquire proficiency in simulations** with Simulx, including comparisons of dosing regimens, evaluation of patient variability, and design of clinical trial scenarios.
- **Practice workflow optimization**, applying presets, automation, and reproducibility tools to streamline modeling tasks and ensure consistency across projects.
- **Build confidence in mlxtran** for writing and adapting models, enabling flexibility in model specification and control of advanced features.
- **Gain hands-on experience with lixoftConnectors in R** to script workflows, automate tasks, and ensure reproducibility of analyses.
- **Apply best practices** in model development, diagnosis, reporting, and regulatory compliance, aligning analyses with FDA and EMA guidelines.

INSTRUCTORS

The workshop is organized and taught by **experienced pharmacometricians and MonolixSuite® specialists from Simulations Plus, Inc.** Simulations Plus, Inc., has been providing clinical pharmacology and pharmacometrics software and consulting services, including population PK/PD modeling and simulation to the global pharmaceutical industry for over 25 years to generate and communicate the knowledge required for time-sensitive decision-making and regulatory review.

AGENDA

8:00–17:30 each day, with lunch 12:15–13:15 and morning & afternoon coffee breaks
Sessions include lectures and hands-on exercises

Day 1: Introduction and Foundations (Thursday, May 14, 2026)

- Principles of the **population approach with NLME models**: when and why to use them
- Fundamentals of **PK and PD modeling**
- Introduction to **MonolixSuite®**: workflow and interface
- Data management: formatting datasets, understanding requirements
- **Data exploration**: visualization, stratification, diagnostics, and identifying variability
- Building the **structural model**: compartmental models, parameters, initial estimates
- Introduction to **Sycomore** for model organization and sharing
- Output files and good practices
- **Mlxtran Part 1**: basics of model coding and syntax

Day 2: Model Development and Evaluation (Friday, May 15, 2026)

- Statistical model: error models, inter-individual variability
- **Covariate analysis**: strategies, stepwise approach, selection criteria
- **Model evaluation and diagnostics**: goodness-of-fit plots, VPC, residuals
- Understanding **algorithm** settings (SAEM, MCMC, etc.) and their impact on performance
- **Plot customization** and use of presets
- **Mlxtran Part 2**: advanced modeling features and flexibility
- **PK/PD modeling approaches**: direct, indirect, and effect compartment models

Day 3: Simulations and Advanced Workflows (Saturday, May 16, 2026)

- Introduction to **Simulx**: setting up simulation scenarios
- Comparing dosing regimens, new populations, clinical trial designs
- **Workflow automation and optimization**: scripting in R using lixoftConnectors
- Compliance with FDA and EMA guidelines in population PK/PD analysis
- Summary discussion, Q&A, and wrap-up

REGISTRATION DETAILS

Course location: The course will be held in person at The Niagara Falls Convention Center (NFCC), 101 Old Falls Street, Niagara Falls, NY 14303. USA. Phone: (716) 278-2100. The Center is 28 minutes from the Buffalo/Niagara International Airport. Website: https://www.niagarafallsusa.com/convention-center/

Accommodations: Several nearby hotels within walking distance are available. Please book directly as soon as registered for this course. Possible hotels: Sheraton Niagara Falls, Quality Hotel & Suites At The Falls, Hyatt Place Niagara Falls, Wingate by Wyndham Niagara Falls, Comfort Inn The Pointe, The Cadence, Seneca Niagara Resort & Casino, Holiday Inn Niagara Falls-Scenic Downtown, The Giacomo, and others including those nearby in Canada.

Fee: The fee is $2800. Graduate student rate (registered MS & PhD) of $1400 is available for up to 5 participants. The registration fee includes access to the course documentation, and code examples. Continental breakfasts, lunches and break-time refreshments during the course are included. No walk-ins accepted.

Requirements: Laptop computers with installed MonolixSuite® are required to fully participate in hands-on exercises. Access to MonolixSuite® will be provided for two weeks from May 11th until May 24th , 2026.

Registration: Online registration will begin **January 26th, 2026**. The course is limited to the capacity of 30 participants. Confirmation email of registration will be returned upon successful registration and payment at the following website: pharmacy.buffalo.edu/pkpd-workshops No walk-ins accepted.

Cancellations: Cancellations with a full refund may be made until **March 16th, 2026**. No refund is possible on cancellations received after this date. Substitutions may be made at any time.

Payment: Mastercard, Visa, American Express, and Discover card payments will be accepted only at the following website: pharmacy.buffalo.edu/pkpd-workshops Contact course secretary: Suzette Mis, (716) 645-4831; mis@buffalo.edu, if you need further assistance.

Social Activities: An evening dinner outing, sponsored by Simulations Plus, Inc. will be offered on Thursday, May 14.

This session is preceded by a PK/PD Modeling course coordinated by Drs. William Jusko, Donald Mager and Dhaval Shah, and is followed by a Monoclonal Antibody PK/PD course coordinated by Drs. Joseph Balthasar and David D'Argenio.
For information see: pharmacy.buffalo.edu/pkpd-workshops or contact Suzette Mis at mis@buffalo.edu.