AN INTRODUCTORY WORKSHOP IN PHARMACOMETRICS USING MONOLIXSUITE®





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



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.