



ACCP

AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY®
Advancing Clinical Care through Pharmacology®

Symposia

MONDAY, SEPTEMBER 16, 2019 | Symposium 6 | 10:00 – 11:30 AM

Model-informed Drug Development for Long-acting Injectable Products

DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #0238-0000-19-006-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Lanyan (Lucy) Fang, PhD, Associate Director (Acting), US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER

Viera Lukacova, PhD, Director, Simulations Plus Inc, Simulation Sciences

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacology and modeling & simulation scientists.

GOALS & OBJECTIVES:

Following the completion of this activity, the learner will be able to:

1. Describe opportunities and challenges in the development of long-acting injectable products;
2. Identify opportunities for model-informed drug development for new and generic long-acting injectable products;
3. Discuss challenges and opportunities from a regulatory perspective.

10:00 – 10:10 AM

Model-informed Drug Development for Long-acting Injectable Products

Lanyan (Lucy) Fang, PhD, Associate Director (Acting), US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER

10:10 – 10:30 AM

Opportunities & Challenges for Modeling & Simulation in Development of Long-acting Injectable Products

Satish Sharan, PhD, Visiting Associate, US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER

10:30 – 11:00 AM

Application of a Physiologically-based Pharmacokinetic Modeling Approach in the Development of Long-acting Injectable Products

Viera Lukacova, PhD, Director, Simulations Plus Inc, Simulation Sciences

11:00 – 11:20 AM

Development of Model-informed Strategies for Long-acting Injectable Products

Mats Karlsson, PhD, Professor of Pharmacometrics, Uppsala Univ, Pharmaceutical Biosciences

11:20 – 11:30 AM

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations