



ACCP

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

Symposia

WEDNESDAY, SEPTEMBER 23, 2020 | Symposium 14 | 10:00 AM – 12:00 PM

Applying Pharmacometrics to Precision Dosing in the Lifecycle of Long-acting Injectable Products: Drug Development, Regulatory Approval & Clinical Practice

QUANTITATIVE TRACK

Offers both CME & CPE Credit

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ACPE – 2 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Hong Lu, PhD, Scientific Director, Takeda Pharmaceuticals USA Inc
Lanyan (Lucy) Fang, PhD, Associate Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

TARGET AUDIENCE:

This Symposium will be useful for drug developers, regulators, physicians and pharmacists.

GOALS & OBJECTIVES:

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

1. Describe the complex pharmacokinetic characteristics of long-acting injectable products that lead to both challenges and opportunities in applying model-informed approaches in development, regulatory approval and clinical dosing practice;
2. Learn a novel quantitative framework for identifying the dose and formulation that maximize the benefit-risk ratio using *in vitro/in vivo* correlation. Apply the modeling strategy to other sustained-release products;
3. Describe the need and approaches for individualized dosing of antipsychotics and discuss the challenges of translating them to a product or tool adopted by healthcare providers in clinical practice;
4. Describe how receptor pharmacology, pharmacokinetics and pharmacodynamics of antipsychotics are combined to optimize clinical outcomes of antipsychotics and apply the proposed thought flow to other disease areas with target-mediated therapy.

Introduction

Lanyan (Lucy) Fang, PhD, Associate Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Clinical Application of Pharmacometrics in Dosing Management of Long-acting Injectable (LAI) Antipsychotics

Hong Lu, PhD, Scientific Director, Takeda Pharmaceuticals USA Inc

Convolution-based Approach for Modeling, Establishing *In Vitro/In Vivo* Correlation & Optimizing the *In Vivo* Drug Release Properties of LAI Products

Roberto Gomeni, PhD, President, PharmacoMetrica & Adjunct Professor, Pharmacotherapy & Experimental Therapeutics, Univ of North Carolina Eshelman School of Pharmacy

Generating Model-integrated Evidence for Developing & Approving Complex Generic LAI Products

Liang Zhao, PhD, Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Role of Pharmacometrics in Guiding Clinical Practice Dosing of LAI Products

Yaning Wang, PhD, Director, Pharmacometrics, Clinical Pharmacology, US Food & Drug Administration

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