FDA Town Hall Update- Modeling and Simulation in GDUFA Regulatory Science Program

Co-Chairs
Lanyan (Lucy) Fang and Lei Zhang

Description
Generic Drug User Fee Amendment (GDUFA) regulatory science funding has spurred significant advancements in understanding the science of equivalence and providing new quantitative tools for drug life cycle management. Quantitative approaches, or computational and analytical tools, have been identified as essential to modernize the drug life cycle management, and new and abbreviated new drug application review processes (refer to FDA public workshop for more information at https://www.fda.gov/Drugs/NewsEvents/ucm554182.htm). Through grants and contracts, the agency has been actively collaborating with leading experts in the fields of physiologically-based pharmacokinetic or absorption models, exposure-response models or clinical trial simulation, systems pharmacology, quantitative risk modeling, big data and machine learning. This FDA town hall meeting will provide updates from the GDUFA-funded modeling and simulation grants/contracts and showcase the regulatory impact of the research outcomes from these modeling grants or contracts.

Learning Objectives
1. Understand the GDUFA research priorities and how research funds are allocated to support projects to develop new quantitative tools
2. Review research outcomes from various GDUFA-funded modeling grants/contracts and provide perspectives on regulatory impact of these outcomes.
3. Understand the critical role of quantitative methods and modeling in drug life cycle management and how to establish broad collaborations among regulatory agency, pharmaceutical industry and academia to further enable computational tools for drug development and regulatory review, risk assessment.
Session Speakers and Presentations

Liang Zhao - Overview of GDUFA-funded Modeling and Simulation grants/contracts

Presentation

Brad Reisfeld - Enhancing the reliability, efficiency, and usability of Bayesian population PBPK modeling

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Joga Gobburu - Population pharmacokinetic and pharmacodynamic, dose-toxicity modeling and simulation for narrow therapeutic index (NTI) drugs

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Narender Singh - A predictive multiscale computational tool for simulation of lung absorption and pharmacokinetics and optimization of pulmonary drug delivery

A predictive multiscale computational tool for simulation of lung absorption and pharmacokinetics and optimization of pulmonary drug delivery