ADVANCING QSP TOWARD PREDICTIVE DRUG DEVELOPMENT: FROM TARGETS TO TREATMENTS

WEDNESDAY, MARCH 13, 2019 | 8:00 AM – 4:45 PM

Co-Sponsors: ASCPT, Innovation & Quality Consortium, the International Society of Pharmacometrics (ISoP), and the US Food and Drug Administration, in collaboration with the National Institute on Aging at the National Institutes of Health.
Chairs: Cynthia J. Musante, PhD; Jane Bai, PhD; and Suzana Petanceska, PhD
FDA Organizing Committee: David Strauss, MD, PhD; Rajnikanth Madabushi, PhD; Justin Earp, PhD; Elimika Pfuma Fletcher, PharmD, PhD; and Jane Bai, PhD
NIH Organizing Committee: Mary Ann Pelleymounter, PhD; and Suzana Petanceska, PhD
IQ Consortium Organizing Committee: Gerald Galluppi, PhD; Mindy Magee, PharmD; and Cynthia J. Musante, PhD

Overview:
Quantitative Systems Pharmacology (QSP) is an emerging field with increasing utilization in recent years. This full-day Pre-Conference will focus on applications of QSP in drug discovery, development, and regulatory reviews. Through presentations and panel discussions, this session aims to raise awareness amongst scientists and decision-makers in academia, the pharmaceutical and biotech industries, and regulatory/funding agencies on:

- The potential value of QSP in drug discovery, development, and review, as illustrated by recent case study examples;
- Real and perceived technical and operational challenges to implementing a QSP approach; and
- Roadblocks and opportunities for greater adoption and acceptance.

This session is aimed for a broad audience; if you are a clinician, executive, scientist, or part of a drug discovery or development team, please join us to find out how QSP can improve decision-making from targets to treatments.

8:00 AM – 8:15 AM
OPENING REMARKS
Jane Bai, PhD, US Food and Drug Administration, Silver Spring, MD
Cynthia J. Musante, PhD, Pfizer, Cambridge, MA
Suzana Petanceska, PhD, National Institute on Aging/National Institutes of Health, Bethesda, MD

8:15 AM – 10:15 AM
SESSION 1: INTRODUCTION AND CURRENT STATUS OF QSP
Session Co-Chairs: Cynthia J. Musante, PhD, Pfizer; and Jane Bai, PhD, US Food and Drug Administration

Introduction to QSP in Drug Discovery and Development: a Historical, Current and Future Perspective
Piet H. van der Graaf, PhD, PharmD, Certara, Canterbury, United Kingdom
Developing a Knowledge Base and Infrastructure to Enable QSP for Alzheimer's Disease Research and Drug Development
Suzana Petanceska, PhD, National Institute on Aging/National Institutes of Health, Bethesda, MD

Trends Towards the Industrialization of Quantitative Systems Pharmacology in Drug Research & Development
Vikram P. Sinha, PhD, Merck & Co. Kenilworth, NJ
Quantitative Systems Pharmacology at the US Food and Drug Administration: From Aspiration to Translation
Issam Zineh, PharmD, MPH, US Food and Drug Administration, Silver Spring, MD

10:15 AM – 10:45 AM
BREAK

10:45 AM – 12:00 PM
SESSION 2: RECENT QSP APPLICATIONS IN DRUG DISCOVERY AND DEVELOPMENT & DECISION-MAKING
Session Chair: Gerald Galluppi, PhD, Sunovion Pharmaceuticals, Marlborough, MA

An Integrative Deep Learning Approach for De Novo Drug Discovery
Joel Dudley, PhD, Institute for Next Generation Healthcare at the Icahn School of Medicine at Mount Sinai, New York, NY
Recent Applications of Quantitative Systems Pharmacology in IQ Consortium: From Data to Decision
Mindy Magee, PharmD, GlaxoSmithKline, Collegeville, PA
Regulatory Perspectives on QSP
Yaning Wang, PhD, US Food and Drug Administration, Silver Spring, MD

12:00 PM – 1:00 PM
NETWORKING LUNCH
Vouchers for hotel food outlets, include Harry's, Stone's Throw, Lobby Lounge & Woodley Pantry

1:00 PM – 2:00 PM
POSTER SESSION

2:00 PM – 3:15 PM

QSP POSTER PRESENTATION AWARD
Presented by Piet H. van der Graaf, PhD, PharmD; Former Editor-in-Chief, *CPT: Pharmacometrics & Systems Pharmacology*

SESSION 3: QSP MODEL ASSESSMENT IN DRUG DISCOVERY, DEVELOPMENT & DECISION-MAKING
Session Chair: David Strauss, MD, PhD, US Food and Drug Administration, Silver Spring, MD

Challenges in Model Qualification: When One Size Does Not Fit All
Stephan Schmidt, PhD, University of Florida, Orlando, FL
Needs and Approaches for Model Assessment & Qualification: A Pharma Perspective
Saroja Ramanujan, PhD, Genentech, South San Francisco, CA
Development and Validation of a Quantitative Systems Pharmacology Model for In Silico Cardiac Safety Assessment under the CiPA Initiative

Zhihua Li, PhD, US Food and Drug Administration, Silver Spring, MD

3:15 PM – 4:35 PM
POINT-COUNTERPOINT AND PANEL DISCUSSIONS: THE PATH FORWARD

3:15-3:30 PM POINT-COUNTERPOINT DISCUSSION
Moderator: Rajnikanth Madabushi, PhD, US Food and Drug Administration, Silver Spring, MD
PANELISTS: Stephan Schmidt, PhD, University of Florida, Orlando, FL; and Vikram Sinha, Merck &Co. Kenilworth, NJ

3:30 PM– 3:55 PM PANEL DISCUSSION: QSP MODEL EVALUATION
Moderator: Justin Earp, PhD, US Food and Drug Administration, Silver Spring, MD
PANELISTS: Saroja Ramanujan, PhD, Genentech, South San Francisco, CA; Stephan Schmidt, PhD, University of Florida, Orlando, FL; Yaning Wang, PhD, US Food and Drug Administration, Silver Spring, MD

3:55 PM - 4:35 PM PANEL DISCUSSION: THE PATH FORWARD
Moderator: Mindy Magee, PharmD, GlaxoSmithKline, Collegeville, PA
PANELISTS: Suzana Petanceska, PhD, National Institute on Aging/National Institutes of Health, Bethesda, MD; Vikram Sinha, PhD, Merck & Co., Kenilworth, NJ; David Strauss, MD, PhD, US Food and Drug Administration, Silver Spring, MD; Piet H. van der Graaf, PhD, PharmD, Certara, Canterbury, United Kingdom; Issam Zineh, PharmD, MPH, US Food and Drug Administration, Silver Spring, MD

4:35PM – 4:45 PM
CONCLUDING REMARKS
Jane Bai, PhD, US Food and Drug Administration, Silver Spring, MD
Cynthia J. Musante, PhD, Pfizer, Cambridge, MA
Suzana Petanceska, PhD, National Institute on Aging/National Institutes of Health, Bethesda, MD