“Model-informed drug discovery and development using Quantitative Systems Pharmacology modeling (QSP): A pharmaceutical industry experience

Speakers: Neil Benson (Certara), Mark Peterson (Pfizer, Inc), John Burke (AppliedBioMath), Jay Mettetal (AstraZenecka), Matt Rizk (Merck and Co., Inc.), and Yaning Wang (FDA).

Organizers: Pratap Singh (Alexion Pharma.) and Jing-Tao Wu (Alnylam Pharma)
Date: 09/29/2017
Time: 8:00 am – 4.10 pm
Location: Boston/Cambridge Area: Marriott Kendall Square, 50 Broadway, Cambridge MA 02142
Fees: $175 - Regular (before Sept 1st, 2017), $225 - Regular (after Sept 1st, 2017); $125 - Unemployed & Academic; $2000 - Major Sponsorship; $475 - Vendor Show
Registration: *www.PBSS.org*

Description:

Quantitative systems pharmacology (QSP) modeling is increasingly being utilized by the pharmaceutical and biotech industry to accelerate drug discovery and development, and facilitate rational decision making. The QSP modeling enables early selection/validation of novel targets, identification of ideal drug properties, preclinical to clinical translation and prediction of biomarker response and efficacy in clinic. It is essentially an extension of standard pharmacokinetic/pharmacodynamic (PK/PD) modeling approaches, and incorporates mechanistic details of drug interaction with its target in physiological context, subsequent pharmacological modulation and effect on disease biomarkers and progression. In this workshop, pharmaceutical/biotech industry’s recent experience in applying QSP techniques for decision making will be highlighted using real world case studies from the fields of inflammation, immuno-oncology, toxicology and antibacterial resistance. Additionally, fresh perspectives on regulatory acceptance and hurdles for QSP modeling will be highlighted by the speakers.

Workshop Agenda and speakers:

- **8:00 – 8:45a** Coffee/breakfast

- **8:45 - 9:00a**: Introductory remarks (*Pratap Singh, Ph.D., Alexion Pharmaceuticals*)
- **9:00 - 9:50a**: Overview and evolution of QSP modeling in pharmaceutical drug discovery and development. (*Neil Benson, Ph.D., Certara*)
- **9:50 – 10:00a:** Word from major sponsor

- **10:00 – 10:20a:** Coffee break

- **10:20 -11:10a:** Model Aided Drug Invention Case Studies in Research: In silico differentiation for dual targeting PD-1 and Tim-3 in I/O, and predicting optimal drug properties of a bispecific biologic to maximize tissue targeting in OA (*John Burke, Ph.D., AppliedBioMath*)
- **11:10 – 12:00p:** Application of QSP/PK/PD in toxicology (*Jay Mettetal, Ph.D., AstraZeneca*)

- **12:00 – 1:00p:** Lunch break

- **1:00– 1:45p**: Leveraging QSP approaches to drive decision-making in drug development and combat the growing threat of antimicrobial resistance- (Matt Rizk, Merck & Co., Inc.)
- **1:45 - 2:30p:** QSP model building and right-sizing of models using Bone Calcium homeostasis model as a case study (Mark Peterson, Ph.D. Pfizer, Inc.)

- **2:30 – 2:50p:** Coffee break

- **2:50 – 3:35p:** Regulatory perspective on mechanistic modeling (Yaning Wang, FDA)
- **3:35 – 4:00p: panel discussion:** How best to quantify the value provided by QSP models? How to make them more impactful? What are the key challenges in realizing full potential of QSP modeling?
- **4:00 – 4:10p:** Closing remarks (Jing-Tao, Ph.D., Alnylam Pharmaceuticals)