ISoP Workshop

Building Mechanistic Physiological Models to Support Decisions in Drug Discovery & Development: A Proven Systems Pharmacology Approach

November 8-9, 2012 in Bridgewater, NJ

Overview

Mechanistic physiological modeling is a proven systems pharmacology approach for improving insight into the mechanisms underlying health, disease, and treatment responses. By integrating data and scientific knowledge from many sources and applying engineering principles, these models enable credible extrapolation beyond limited proprietary, compound-specific data. Customized models are built with a focus on supporting drug development decisions and enable systematic investigation of hypotheses and simulation of what-if scenarios. Such models have been used successfully for evaluation of target, optimization compound, translation from *in vitro* and preclinical studies into human applications, optimization of trial design, and identification of biomarkers and responder populations.

Educational Objectives

In this workshop, participants will learn what mechanistic physiological models are, how they are built, and how they can be applied. They will also learn the Model Qualification Method (MQM), a systematic approach for ensuring that a model is fit for the purpose for which it is intended. Participants will work hands on a) planning a successful modeling project for an example drug development question, b) scoping the relevant biological components for inclusion, c) translating biological relationships into mathematical equations, d) analyzing data from literature for use in the model, e) running simulations, f) performing sensitivity analysis, g) creating multiple "virtual patients" to address uncertainty and variability, h) interpreting model results, and i) testing the model qualitatively and quantitatively.

Purpose and Final Results for the Participants

Participants will emerge with a perspective on modeling that focuses on drug development decision support, balancing the need to provide credible scientific insights with limited time and resources. Workshop attendees will learn to use JDesigner, a mechanistic modeling program that is developed by and freely available from the University of Washington, and will leave the workshop with the demonstration model.

Register: http://www.go-isop.org/attend

Instructor

Dr. Christina Friedrich is Chief Engineer, PhysioPD™, at Rosa & Co. Dr. Friedrich is responsible for the engineering methods and processes throughout in Rosa's PhysioPD practice. She has over 10 years of experience in developing and applying mathematical models of biologic/physiologic systems to product development issues faced by biotechnology, pharmaceutical, and consumer product companies, spanning a range of disease areas including diabetes, blood disorders, rheumatoid arthritis, other immune system dysfunctions and inflammatory processes, and skin disorders. Before joining Rosa, Dr. Friedrich was the Director of Core Product Development at Entelos, Inc., where she designed and led the development of models in new disease areas, extended existing models into new markets, pioneered numerous methodologies, and led large research collaborations with bio-pharmaceutical and consumer products companies. Dr. Friedrich received her Ph.D. in Management Science & Engineering from Stanford University.