



Monday  
October 7, 2013  
9:00 AM - 4:00 PM  
Sheraton Bucks County Hotel

Instructor:



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Pfizer

## Assessment of Oral Bioavailability in Preclinical Species and Human: Impact of Physicochemical, Biopharmaceutical and Physiological Factor

Poor oral bioavailability is one of the leading causes of compound failure in preclinical and clinical development. Compounds with poor oral bioavailability and short half life tend to have large dose and higher inter and intra-individual variability, which would limit their therapeutic usefulness and increase the cost of their developments. Poor oral bioavailability in preclinical species does not necessarily translate into poor human oral bioavailability and vice versa. This practical/hands on course is specifically designed for personnel in the pharmaceutical and biotechnology industries and contract research organizations (CROs), who need to understand:

- General principles of pharmacokinetics
- The parameters that determine oral bioavailability in human
- Approaches to optimize physicochemical and biopharmaceutical parameters that influence drug solubility, permeability, and metabolism, where applicable
- Anatomical and physiological factors that lead to species differences in oral bioavailability
- The state-of-the-art in vitro and in vivo ADME assays, and how pharmacokinetics, and drug metabolism and transporter research studies are conducted to select the candidates to advance in preclinical and clinical development
- The utility of validated physiologically based pharmacokinetics (PBPK) modeling during discovery and development of drug candidates
- The use of Biopharmaceutics Drug Disposition Classification System (BDDCS) in predicting drug disposition, drug-drug interaction, and impact of food on the pharmacokinetic profile of new chemical entities (NCEs)

The workshop will also include a hands-on session that aims at improving your ability to apply these strategies to medicinal chemistry for hit selection, lead optimization, and development candidate selection

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