“Preclinical Development & IND Filing: Nuts, Bolts, Best Practices and Regulatory Aspects.”

Speakers: Amit Kalgutkar (Pfizer), Chandra Prakash (Agios), Sanjeev Thohan (Novartis), Li-Chun Wang (Takeda), Wei Yin (Biogen)
Organizers: Sanjeev Thohan and Chandra Prakash
Date: 6/29/2017
Time: 8:30 am – 5.00 pm
Location: Boston/Cambridge Area: Marriott Kendall Square, 50 Broadway, Cambridge MA 02142
Fees: $175 - Regular (before June 1st, 2017), $225 - Regular (after June 1st, 2017); $125 - Unemployed & Academic; $2000 - Major Sponsorship; $475 - Vendor Show
Registration: www.PBSS.org

Workshop Description:

An investigational new drug application (IND) is an important milestone that marks the entry of a molecule into clinical development. Knowing the objectives, expectations and processes of assembling an IND is a key to not only successful filing, but also a promising clinical development path forward. Often there are cases where too many of our “nice-to-have” studies crowd the package at the expense of critical study needs/issues. This can lead to significant delays in clinical developments with back-and-forth of Q&A sessions both internally and with regulatory agencies. As we have seen, the regulatory landscape is changing as rapidly as the industry innovates into new therapeutic modalities. Therefore, it is critical to keep up to date on regulatory requirements and the industry’s best practices in different aspects of the IND: non-clinical safety, PK, CMC, and clinical plans. In this workshop, our speakers who bring years of experience with multiple successful IND filings, will discuss systematically the preclinical studies required for small molecule IND’s as well as the nuts and bolts of putting together a high–quality IND package. We will also discuss some strategies for interaction with various regulatory agencies. The following topics will be presented with ample opportunity for discussion

- Overview of preclinical development and regulatory requirements for IND filing
- Disciple specific preclinical study requirements (Pharmacology, Pharmacokinetics and Drug Metabolism and Toxicology)
- Chemistry, Manufacturing and Control (Early Dose Form Selection, Formulation Selection and Optimization Over the Life Cycle of the Development Program)
- Clinical development plans
- Interfacing with the regulatory agencies (FDA and EMEA)
About the Speakers

Amit Kalgutkar, Ph. D. (Pfizer)
Dr. Kalgutkar received his Ph.D. degree in Chemistry from Virginia Tech. He then pursued post-doctoral studies at the Department of Biochemistry, Vanderbilt University prior to joining Pfizer in 1999. Dr. Kalgutkar has over 17 years’ experience in drug discovery/development, spanning multiple therapeutic areas. In his role as a drug metabolism scientist, Dr. Kalgutkar has been involved in the discovery and nomination of over a dozen clinical candidates including the SGLT2 inhibitor and anti-diabetic agent Ertugliflozin, which is currently under review by the United States FDA. Dr. Kalgutkar is an accomplished scientific leader inside Pfizer as well as in the external scientific community with over 150 peer-reviewed papers, reviews and book chapters and 8 issued patents. He is currently on the editorial boards of Chemical Research in Toxicology (American Chemical Society), Drug Metabolism and Disposition and Xenobiotica. Dr. Kalgutkar currently holds the title of Research Fellow. Dr. Kalgutkar also serves as an Adjunct Professor at the Department of Biomedical and Pharmaceutical Sciences, School of Pharmacy, University of Rhode Island.

Chandra Prakash, Ph.D. (Agios)
Dr. Prakash is a Senior Research Fellow in Drug Metabolism, Pharmacokinetics and Clinical Pharmacology Department at Agios, Cambridge, MA. Prior to joining Agios, he worked at Vanderbilt University (Nashville, TN), Pfizer Global Research and Development (Groton, CT) and Biogen (Cambridge, MA). For the last 30 years, Dr. Prakash has been involved in the drug metabolism and clinical pharmacology studies to support drug discovery, development and registration. His research is primarily focused on the development and utilization of novel approaches and techniques which include in vitro methods using human and animal hepatic cellular and subcellular systems, recombinant human drug metabolizing enzymes, sensitive analytical technologies and in silico computational models to assess the metabolism and toxicological aspects of the new chemical entities. He has also expanded research efforts to develop label free tissue distribution of parent compounds and their metabolites and identification of biomarkers using MS imaging. He is the author of more than 265 manuscripts, book chapters, presentations and patents. He also coedited five volumes of Handbook of Metabolic Pathways of Xenobiotics. He served as the editor-in-chief of the Journals “Current Drug Metabolism” and "Drug Metabolism Letters" (2000-2015) and editorial board member of Annals of Medicinal Chemistry and Research, Current Biotechnology and journal of Pharmaceutics. He served as the chair of ISSX publication committee and recently as a member of ISSX financial committee.

Sanjeev Thohan, Ph.D. (Novartis)
Dr. Thohan is a Senior Research Fellow in Preclinical/Translational Sciences at the Novartis Institutes for BioMedical Research in Cambridge, MA. Prior to this role, he served as the Director of Non-Clinical Discovery/Development at Exelixis Inc in South San Francisco, CA. He holds MS and PhD degrees in Pharmacology and Toxicology from the University of Arizona and University of Maryland with concentrations in interspecies drug metabolism mechanisms, bioactivation, and systems toxicology. His broad background from research units at Walter Reed Army Institute for Research, Covance, AstraZeneca, ViroPharma, and Exelixis allows him a unique vantage point to discovery-development based non-clinical research activities. During his research career, he has facilitated over 27 compounds into clinical trials in the Anti-viral,
Oncology, Metabolic and Cardiovascular Diseases therapeutic areas.

**Wei Yin, Ph. D. (Biogen)**

Dr. Yin is Associate Director of Clinical and Quantitative Pharmacology at Biogen. Formerly, she held various positions within the Clinical Pharmacology and Drug Metabolism and Pharmacokinetics divisions at companies including Vertex and Takeda Pharmaceuticals. Dr. Yin is a member of a number of professional societies, including the Oligonucleotide Therapeutics Society, the American Association of Pharmaceutical Scientists, the American College of Clinical Pharmacology, the American Society for Clinical Pharmacology and Therapeutics, and the American Conference on Pharmacometrics. Dr. Yin received her BS in pharmacy from Peking University Health Science Center and Ph.D. in Pharmacokinetics and Pharmaceutical Sciences from the University of Texas at Austin. She has presented and published in the area of clinical pharmacology and Drug Metabolism and Pharmacokinetics.

**Li-Chun Wang, Ph.D. (Takeda)**

Dr. Wang is Director of Global Regulatory Affairs CMC, Small Molecules at Takeda, Cambridge, MA. Prior to joining Millennium (Takeda), she worked at Bristol-Myer Squibb, Cater Wallace, etc. In her over 30 years pharmaceutical experiences, she had worked in many facets of product development encompassing Preformulation/Analytical Support, Sterile and Semi-solids Manufacturing Process and Technology Transfer, Commercial QC/QA, Generic Development, and Regulatory CMC for NCE and marketed products. For the last 11 years in Regulatory, Dr. Wang had successfully secured NDA/MAA and rest of world approvals, led FDA meetings, executed CMC submissions to support global clinical trials (IND, IMPD, CTA, amendment, etc.) and marketed products (AR, renewals, variations, etc). Dr. Wang received her BS in pharmacy from National Taiwan University and Ph.D. in Pharmaceutical Sciences from University of Connecticut, CT. She was invited speaker to several conferences on new drug development and regulatory in Taiwan and has served in AAPS Membership Strategic Oversight Committee and Regulatory Science Section in 2013.