Drug Development Processes & Regulatory Approaches

One Week Training Program

Date: June 11-15th 2012
Venue: University of Maryland Schools of Pharmacy
20 N. Pine Street, Baltimore, MD 21201

Organizer

JG Business Link International

University of Maryland School of Pharmacy

Support

State of Maryland Business Office-Korea(SOMBOK)

Food and Drug Administration(FDA)

Program Introduction

One-week training program for Korea's discovery/drug development, regulatory scientists, and industrial pharmaceutical scientists interested in understanding the drug development process, regulatory aspects of this process in the U.S., and biosimilar guidance from the U.S. Food and Drug Administration – for further regulatory harmonization from the KORUS Free Trade Agreement

Target Audience

Korea's leading pharmaceutical company executives, academic researchers, and governmental regulatory and economic development officials

Leaning Objectives

- **To understand the scientific, clinical and regulatory process used in the development of drugs for the treatment of various diseases (e.g., HIV, hypertension, cardiovascular disease, lipid lowering agents).**
- **To review the content required for a Clinical protocol (Phase I-III) from the perspective of IRB policies, regulator policies and the pharmaceutical industry.**
- **To review the content preclinical, toxicological and clinical protocol that comprise and IND and NDA**
- **To review various pertinent FDA guidances that are critical to the drug design process and streamlining of this process.**
- **To review the current FDA draft guidances on biosimilars released on February 9th, 2012.**

In addition, the program participants will have the opportunity to meet individually with leading faculty from UMB's Schools of Pharmacy, Medicine, Nursing, and Dentistry to discuss specific clinical trials and research collaborations.

Course Overview

This course provides the clinical, scientific and regulatory perspective on design, development and evaluation of new chemical entities. The target audience for this course is clinical and regulatory officers and Korean pharmaceutical companies, drug reviewers, and biotechnology scientists. The course will focus on the drug development process from Investigational New Drug Application (IND) to a New Drug Application (NDA) for various diseases (e.g., HIV/AIDS, depression, hypertension, cardiovascular agents). This will be accomplished by "real world" examples for an industrial and regulatory perspective that focus on Phase I-IV protocol development and study implementation. Protocol review will also be presented from an institutional Review Board perspective by the use of a mock IRB session. The course will also provide a regulatory review of Pre-clinical studies including pharmacology and toxicology, Phase I studies (e.g., single dose ADME, dose proportionality, and drug interactions), Phase II studies (clinical trials in small number of patients) and pivotal Phase III studies (clinical trials in large number of patients). Critical regulatory guidances will be presented Food Effect studies, Biomarkers in Clinical Drug Development, Exposure-Response, Scale-Up and Post Approval Changes. The impact of Pharmacoeconomics on drug development will be presented.

The course introduces FDA guidances of biomarker development and validation of case studies, bioequivalence-switchability, and biosimilars. On February 9th 2012, draft guidance regarding regulations of biosimilars at the US FDA was completed. With the Korea-USA Free Trade Agreement taking effect, the Korean pharmaceutical industry will be adversely affected by US pharmaceutical regulations if harmonization is not completed. Through this course paths to understanding the U.S regulations and policies of pharmaceuticals and biosimilars in IRB and U.S FDA will promote further Korean pharmaceutical development.

This course will be led by faculty from the University of Maryland Schools of Pharmacy and Medicine, as well as officials from the U.S. Food and Drug Administration. The course is arranged by JG Business Link International.

PROGRAM (June 11-15, 2012)

Date	Time	Program
June 11, 2012 (Mon)	**9:00-9:30 am**	**Opening/Welcome (Organizers)**
	9:30-12:00 pm	**Drug Development Process** Faculty: **Natalie D. Eddington,** PhD, Dean and Professor of Pharmaceutical Sciences; Director of Pharmacokinetics Laboratory, University of Maryland School of Pharmacy **IND Process - Nonclinical** •DME and transporter studies guidance •Pharmacology and Toxicity study design and guidance •Rodent study design •Determination of LD50 •Case Studies in Pharmacology and Toxicology Faculty: **Ken Bauer**, PharmD, PhD; Associate Professor of Pharmacy Practice and Science, Director of Clinical Pharmacology Unit, University of Maryland School of Pharmacy **Peter Swaan,** PhD; Professor of Pharmaceutical Sciences; Director of Center of Nanomedicine and Cellular Delivery, Associate Dean of Research and Gradaute Education; University of Maryland School of Pharmacy **Hongbing Wang**, PhD.; Associate Professor of Pharmaceutical Sciences, University of Maryland, School of Pharmacy
	12:30-1:00 pm	**Lunch**
	1:00-5:00 pm	**CMC Process** •USP Identification Standards •Chemistry Section •Specifications for CMC •FDA Pertinent Guidances

		Faculty: ***Vibhakar J. Shah**, Office of New Drug Quality, Center for Drug Evaluation Research, Food and Drug Administration* **Stephen Hoag,** PhD; Professor of Pharmaceutical Sciences; Director of cGMP Laboratory, National Institute of Pharmaceutical Technology and Education, University of Maryland School of Pharmacy **IND Process – Clinical Studies** •PBPK extrapolation studies to Man •First Time in Man studies (protocol design) •IRB Processes and requirements – case studies •Case Studies and FDA pertinent guidance review Faculty: **Deanna L. Kelly**, Pharm.D., BCPP; Associate Professor of Psychiatry; Director and Chief, Treatment Research Program (TRP); Maryland Psychiatric Research Center; University of Maryland School of Medicine **Jia Bei Wang,** PhD; Professor of Pharmaceutical Sciences, University of Maryland, School of Pharmacy **Mohamed S. Al-Ibrahim**, MD; Chief Medical Officer and President, SNBL Clinical Pharmacology Center
June 12, 2012 (Tue)	**9:00-12:00 pm**	**Clinical Study Design Phase I, Phase II, Phase IIA, Phase III – Drugs Protocol Design, power analysis,** •Drug Classes -- Antimicrobials, Antihypertensives, Cardiovascular, Antipsychotics, •Historical controls, placebo controls, standard therapy controls – study •IRB Processes and requirements – case studies •Biomarker Development and Validation •Clinical Case Studies and Pertinent FDA Guidance review Faculty: ***Islam Younis**, PhD; Senior Reviewer, Office of Clinical Pharmacology, Center of Drug Evaluation Research, Food and Drug Administration* **Deanna L. Kelly**, Pharm.D., BCPP; Associate Professor of Psychiatry; Director and Chief, Treatment Research Program (TRP); Maryland Psychiatric Research Center; University of Maryland School of Medicine **Michael L Terrin** M.D.,C.M., M.P.H, Professor of Epidemiology and Public Health, University of Maryland School of Medicine
	12:00 – 1:00pm	**Lunch**
	1:00-5:00pm	**Clinical Study Design Phase I, Phase II, Phase IIA, Phase III – Drugs (Cont'd)**

June 13, 2012 (Wed)	**9:00am – 12:00pm**	**Pharmacometrics and Clinical Trials Design** •Data Analysis, Pharmacometrics and Clinical Trial Design •Statistical methodology for design, and evaluation of Clinical Trials •Use of SAS, population modeling, PK/PD modeling •Case Studies and pertinent FDA Guidances Faculty: **Joga Gobburu,** PhD, Professor of Pharmacy Practice and Science, Director Center of Translational Sciences, University of Maryland School of Pharmacy (Note: formerly Director of Pharmacometrics, Center of Drug Evaluation Research, Food and Drug Administration)
	12:00-1:00 pm	**Lunch**
	1:00-5:00 pm	**Pharmacometrics and Clinical Trials Design (Cont'd)**
June 14, 2012 (Thur)	**9:00-12:00 pm**	**Bioequivalence** •ANDA Process and Hatch-Waxman Law •Orange Book designations •Narrow Therapeutic Index Drugs •Old drug exceptions •Bioavailability study design •Bioequivalency study design Dissolution, SUPAC and IVIVC Bioequiavalence – switchability (narrow therapeutic indices) Review of pertinent FDA guidances – SUPAC and IVIVC Faculty: **Mehul Mehta**, PhD; Director of Clinical Pharmacology, Center of Drug Evaluation Research, Food and Drug Administration **Francis B. Palumbo,** PhD, JD; Professor of Pharmaceutical Health Services Research; Executive Director; Center of Drugs and Public Policy, University of Maryland School of Pharmacy **James E. Polli,** PhD. Ralph Shangraw Professor of Pharmaceutical Sciences; Director of the Food and Drug Administration Center of Excellence in Regulatory Science and Innovation, University of Maryland, School of Pharmacy
	12:00-1:00 pm	**Lunch**
	1:00-5:00 pm	**Bioequivalence (Cont'd)**

June 15, 2012 (Fri)	**9:00am – 12:00pm**	**Biologicals and Biosimilars** •Clinical Study Design Phase 1- 3- Biologicals •Protocol Design, Drug Classes – TNF inhibitors, anticancer agents, anti-arthritis agents •Biomarker Development and Validation •Biosimilars/follow on biologics; pertinent FDA guidances Faculty: **Joga Gobburu,** PhD, Professor of Pharmacy Practice and Science, Director Center of Translational Sciences, University of Maryland School of Pharmacy (Note: formerly Director of Pharmacometrics, Center of Drug Evaluation Research, Food and Drug Administration) **Francis B. Palumbo**, PhD, JD; Professor of Pharmaceutical Health Services Research; Executive Director; Center of Drugs and Public Policy, University of Maryland School of Pharmacy
	12:00-1:00 pm	**Lunch**
	1:00-5:00 pm	**Group Discussions and Q & A Session** **Closing Ceremony** **Certification**

Seminar Services & Admission Fee

During this seminar, speakers from the University of Maryland School Of Pharmacy, University of Maryland School of Medicine, and the U.S. Food & Drug Administration will be provided.

Attendees will also be provided for all five program days from June 11-15:

Handouts
Programs
Breakfast
Lunch
2 Coffee Breaks

Space at the University of Maryland School of Pharmacy will also be provided along with the audio-visual presentations.

The total cost for this program is: $5,000 USD per Attendee

Additional Services

Additional services for transport (to and from the hotel and airport), hotel accommodations, evening meals and breakfast prior to departure, and an additional guide can be provided for and additional: $1,000 USD per Attendee

If there are any questions, please contact JG Business Link International at +1 301-528-2200 or at contact@jgbli.com.

We look forward to your participation and success from this seminar.