M-CERSI

SECOND ANNUAL M-CERSI DAY

SEPT. 5, 2013 • 8:30 A.M. - 1 P.M.

OPEN PROGRAM

8:30-9 a.m.
Breakfast and Registration

9-9:15 a.m.
Welcome and Introduction

JAMES POLLI, PHD
Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics
University of Maryland School of Pharmacy

WILLIAM BENTLEY, PHD
Robert E. Fischell Distinguished Professor and Chair
Fischell Department of Bioengineering
University of Maryland, College Park

FRANK WEICHOLD, MD, PHD
Director of Regulatory Science and Innovation
Food and Drug Administration

NATALIE D. EDDINGTON, PHD, FAAPS, FCP
Dean and Professor
University of Maryland School of Pharmacy

9:15-9:40 a.m.
A Bayesian Adaptive Trial for CER: Case Study in Status Epilepticus

JASON CONNOR, PHD
Statistical Scientist
Berry Consultants

9:40-10:05 a.m.
Improving Consistency through Product Review Modernization

CHARLES "CHUCK" COOPER, MD
Deputy Director, Office of Computational Science in the Office of Translational Science
Food and Drug Administration (FDA)

10:05-10:30 a.m.
Biomarker as a Drug Development Tool and Biomarker Qualification at FDA/CDER

SHASHI AMUR, PHD
Biomarker Qualification Scientific Coordinator
Food and Drug Administration

10:30-11 a.m.
Break

11-11:25 a.m.
Streamlining the Development and Approval Processes for 505(B)(2) NDA Applications

SANJAY SEHGAL, PHD
Managing Director
Aexelar Regulatory Experts, Inc.

11:25-11:50 a.m.
Research Initiatives in the FDA's Office of Generic Drugs

ROBERT LIONBERGER, PHD
Acting Deputy Director for Science
Office of Generic Drugs
Food and Drug Administration

11:50 a.m.-1 p.m.
Lunch and Poster Session

CLOSED SESSIONS

Afternoon meetings are open only to FDA and University of Maryland content experts, Steering Committee members, Advisory Panel members, and CERSI Industrial Consortia members.

1-2:30 p.m.
Project 1:
Improving Pre-Clinical Assessments of Safety and Efficacy
Location: Room N208

1-2:30 p.m.
Project 2:
Ensuring Readiness
Location: Room S410

1-2:30 p.m.
Project 3:
Harnessing Diverse Data
Location: Room N310

1-2:30 p.m.
Project 4:
Minority Health
Location: Room S103

2:30-3:30 p.m.
Feedback from and wrap-up with M-CERSI Advisory Panel and Industrial Consortia members
Location: Room N203

FOR MORE INFORMATION

PLEASE VISIT *WWW.CERSI.UMD.EDU.*

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SPEAKER BIOS

JASON CONNOR, PHD, works for Berry Consultants designing Bayesian adaptive clinical trials. He is also an assistant professor of medicine at the University of Central Florida College of Medicine and a visiting professor at the Johns Hopkins University School of Public Health. Dr. Connor earned his BS in biomedical engineering from Texas A&M University and his PhD in statistics and in public policy from Carnegie Mellon University.

CHARLES "CHUCK" COOPER, MD, is a board-certified infectious disease specialist who for several years served as a clinical reviewer in the Division of Anti-Infective Products in the Center for Drug Evaluation and Research (CDER) at the FDA. He then spent three years in the FDA's Quantitative Safety and Pharmacoepidemiology Division in the Office of Biostatistics. He currently is deputy director in CDER's Office of Computational Science in the Office of Translational Science and is focused on initiatives aimed at modernizing the drug review process. This work includes review software/tool/service development and deployment, as well as development of the associated underlying data standards. He practices at Greater Baden Medical Services where he provides care to HIV patients. Dr. Cooper is a graduate of Georgetown Medical School and did his residency training at Strong Memorial Hospital, University of Rochester, and a fellowship at the University of Maryland, Baltimore.

SANJAY SEHGAL, PHD, serves as the managing director at Aexelar Regulatory Experts, Inc., in Exton, Pa. Dr. Sehgal has strategized, guided, and authored multiple global registration dossiers and has negotiated approvals for eight New Drug Applications (NDAs) including a 505(B)(2) drug-device combination. Recently, he led the review and approval processes for a resubmitted 505(B)(2) NDA along with the associated labels (PI, carton, co-package), advertising and promotional materials, and adverse event reporting to the FDA.

SHASHI AMUR, PHD, received her doctoral degree in biochemistry from the Indian Institute of Science in Bangalore, India, and completed postdoctoral fellowships at Temple University and the University of California, Los Angeles. She then gained experience in diagnostic and biotech sectors at Specialty Laboratories in Santa Monica, Calif., at Applied Biosystems in Foster City, Calif., and at Neotropix Inc. in Malvern, Pa., before joining the Center for Drug Evaluation and Research (CDER) at the FDA as a senior genomics reviewer in the Office of Clinical Pharmacology (OCP). Dr. Amur has been an invited speaker at national and international conferences and is the author of several scientific publications. Her current research interest areas include pharmacogenomics, HLA-associated adverse events, and biomarkers in autoimmune diseases and in Alzheimer's disease. Dr. Amur has served as chair of the Pharmacogenomics Science Interest Group and the OCP Science Day Committee at OCP/CDER/FDA and has organized seminars and workshops in CDER/FDA. She is currently the chair of the American Association of Pharmaceutical Scientists' Pharmacogenomics Focus Group.

ROBERT LIONBERGER, PHD, is acting deputy director for science in the Office of Generic Drugs (OGD) at the FDA. He received his undergraduate degree in chemical engineering from Stanford University and a PhD in chemical engineering from Princeton University, working on modeling the rheology of colloidal suspensions. After his PhD, he completed two years of postdoctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA, he was an assistant professor of chemical engineering at the University of Michigan, where he was involved in the development of a new pharmaceutical engineering program. At the FDA, his accomplishments include the development of bioequivalence methods for locally acting drugs, mathematical modeling of drug dissolution and absorption, and incorporation of product and process development information into the Abbreviated New Drug Application (ANDA)-Chemistry, Manufacturing, and Controls (CMC) review process. He is currently leading OGD's implementation of the Generic Drug User Fee Amendments regulatory science commitments.