M-CERSI

CERSI DAY

SEPTEMBER 5, 2012 • KIM ENGINEERING BUILDING

OPEN PROGRAM

8:30-9:00 AM	Light Breakfast
9:00-9:15 AM	**Jesse Goodman, MD, MPH (FDA)** - Introductory Comments
9:15-9:40 AM	**Rob Conley, MD (Lilly)** - Devices and Human Factors
9:40-10:05 AM	**James McElvain, PhD (Kythera Biopharmaceuticals)** - GMPs in Early Development
10:05-10:30 AM	**Jack Cook, PhD (Pfizer)** - Paradigm Shift in Drug Development of Anti-infectives and Treatments of Rare Diseases
10:30-11:00 AM	Coffee Break
11:00-11:25 AM	**Steve X. Castellino, PhD (GlaxoSmithKline)** - MALDI Imaging Mass Spectrometry: Bridging Biology and Chemistry in Drug Development
11:25 AM-1:00 PM	Lunch and Posters (including CERSI Innovation Award Posters)

CLOSED MEETINGS

Afternoon meetings are open only to FDA and University of Maryland Content Experts, Steering Committee Members, Advisory Panel Members, and CERSI Industrial Consortia Members for participation.

1:00-2:30 PM	Meeting of Project 1: Improving Pre-Clinical Assessments of Safety and Efficacy
1:00-2:30 PM	Meeting of Project 2: Ensuring Readiness
1:00-2:30 PM	Meeting of Project 3: Harnessing Diverse Data
2:30-3:30 PM	Feedback from Industrial Consortia Members and Advisory Panel Members

FOR MORE INFORMATION, PLEASE VISIT US AT WWW.CERSI.UMD.EDU

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SPEAKER BIOS

Jesse Goodman, MD, MPH (FDA) is the FDA's Chief Scientist. In this capacity, he is responsible for leading and coordinating FDA's cross-cutting scientific and public health efforts, among which has been the FDA response to the H1N1 pandemic. The Office of the Chief Scientist works closely with FDA's Centers, providing strategic leadership and support for FDA's regulatory science and innovation initiatives. These initiatives include the Critical Path Initiative, scientific professional development, scientific integrity, and the Medical Countermeasure Initiative. Dr. Goodman's first position with the FDA was as Senior Medical Adviser to the Commissioner in 1998. In that role, he initiated and co-chaired the U.S. Government-wide Task Force that issued the nation's first Public Health Action Plan to Combat Antimicrobial Resistance. He joined FDA full-time in 2001 as Deputy Director of the Center for Biologics Evaluation and Research (CBER), becoming Director in 2003. A graduate of Harvard, Dr. Goodman received his M.D. from the Albert Einstein College of Medicine and completed his residency and fellowship training at the Hospital of the University of Pennsylvania and at UCLA, where he was also Chief Medical Resident. Prior to joining FDA, he was Professor of Medicine and Chief of Infectious Diseases at the University of Minnesota, where he directed its multi-hospital research, training and clinical infectious diseases program.

Rob Conley, MD (Lilly) is the Regulatory Leader for Biomedicines at Eli Lilly & Company and Distinguished Lilly Scholar in Neuroscience. He leads the late phase regulatory group responsible for Psychiatry, Neurology, Cardiology, Urology, Men's Health, Bone/Muscle/Joint Disorders and Autoimmune Disorders, as well as advising on all phases of Neuroscience development. He was, until 2008, the Chief of Treatment Research at the Maryland Psychiatric Research Center. His current research work focuses on the basic understanding of the neuroanatomy and physiology associated with severe mental illness, and the health outcomes of people with severe mental illness. He has been the principal investigator of studies sponsored by the National Institute of Mental Health, the National Institute on Drug Abuse, the Stanley Research Foundation and The National Alliance for Research in Schizophrenia and Affective Disorders. He is the past Chairman of the Institutional Review Board for the National Institute on Drug Abuse and also the University of Maryland, Baltimore and is now a lead member of the Bioethics Advisory Committee at Lilly. He has authored over 200 papers in publications such as the *Journal of Psychopharmacology*, the *American Journal of Psychiatry*, *Archives of General Psychiatry*, *Schizophrenia Research*, and the *Journal of Clinical Psychopharmacology*. He is the Founding Editor of *Clinical Schizophrenia & Related Psychoses*.

James McElvain, PhD (Kythera Biopharmaceuticals) is Senior Director and Head of the Analytical and QC Department at Kythera Biopharmaceuticals in Calabasas, California. His primary responsibilities involve directing and overseeing the development and implementation of analytical methodology to quantitate and characterize novel small molecule therapeutics during R&D product development and commercialization. Prior to joining Kythera, Dr. McElvain held various small molecule analytical and bioanalytical leadership positions at Amgen in Thousand Oaks, CA and Hoechst Marion Roussel in Kansas City, MO. He has a B.S. degree in Biochemistry from California Polytechnic State University in San Luis Obispo and M.S. and Ph.D. degrees in Biochemistry from Washington State University. Dr. McElvain has served as past chair of the PhRMA Analytical Technical Group (ATG) and is the current chair of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) Analytical Leadership Group (ALG).

Jack Cook, PhD (Pfizer) is Vice President, Clinical Pharmacology Specialty Care at Pfizer, Inc., Groton, CT. Additionally, Dr. Cook is an Adjunct Professor in the College of Pharmacy at the University of Michigan. He received an A.A.S degree in Industrial Chemistry Technology (1978), and B.S. degrees in Applied Mathematics (1981) and Pharmacy (1981) from Ferris State College; and Ph.D. degree in Pharmaceutics from the University of Michigan (1987). Dr. Cook started his career with Sterling Drug Inc. in Albany, NY in 1981. In 1987 he joined Parke-Davis which later became Pfizer, Inc. Dr. Cook's areas of technical expertise are in biopharmaceutics, pharmacokinetics, pharmacodynamics, modeling and statistics. He is a member of the American Association of Pharmaceutical Scientists and on the Board of Directors for the Drug Delivery Foundation. His current interests include improving therapy by optimizing drug delivery and the use of modeling and simulation to make rational decisions in the development of drugs. He has published 51 original research articles and 3 book chapters.

Steve X. Castellino, PhD (GlaxoSmithKline) received his BA degree in Chemistry from California State University at Long Beach in 1979 and Ph.D. degree in Organic Chemistry from the University of California, Riverside in 1984. His graduate research focused on the structural characterization and synthesis of marine natural products. Dr. Castellino accepted a post-doc position at the University of Utah in Professor Gary Keck's lab where he investigated the application of NMR to elucidate the structural elements controlling diastereofacial selectivity in stannane additions to aldehydes. After a short post-doctoral position at Monsanto, he then took a faculty position at North Dakota State University. His research program was aimed at elucidating the structure of Lewis acid complexes involved in stereochemical transformations by NMR. In 1993, Dr. Castellino headed to the warmer climate of North Carolina and joined Rhone-Poulenc where he headed up the NMR group and later became spectroscopy group team leader. In 1997, Dr. Castellino moved across the street to join the drug metabolism group of GlaxoWellcome. He is currently Director of Drug Metabolism and Pharmacokintics. His team is responsible for the structural elucidation of drug metabolites in development programs at GlaxoSmithKline.