

Manufacturing PET Radiopharmaceuticals

Special Workshop organized by CMOD in collaboration with SNM

AGENDA, May 1, 2009

6:10 PM - 6:20 PM Introduction and Overview

Peter Libby, Brigham and Women's Hospital; Donald M. Black, GEHC Diagnostics; Michael M. Graham, U of Iowa

6:20 PM - 6:40 PM PET Drug Regulation: A Brief History

Dennis Swanson, University of Pittsburgh

6:40 PM - 7:00 PM Review of Current USP Chapter 823 for IND and RDRC Regulated PET Compounding

Sally Schwarz, Washington University

7:00 PM – 7:20 PM Current Regulatory Draft Guidelines for PET Drug Products

Eldon Leutzinger, Chemistry Team Leader, Medical Imaging, FDA

7:20 PM - 7:40 PM Applying Current Guidelines: Challenges and Successes

Luke Augustine, PharmD, Cardinal Health

7:40 PM - 8:00 PM CGMP Compliance with a Centralized IND – Comparison of FDA PET CGMP and USP <823> Requirements

Joseph Hung, Mayo Clinic

8:00 PM – 8:20 PM The Development and Commercialization of New PET Tracers

Donald Black, Head R&D GEHC Diagnostics

8:20 PM – 8:40 PM Introduction to the SNM Clinical Trials Network: CMC Compliance with a Multicenter IND

George Q. Mills, Perceptive Informatics

8:40 PM - 9:45 PM Q & A and Guided Panel Discussion



The International Partnership for Critical Markers of Disease (CMOD) is a non-profit I.R.S. 501(c)3 tax exempt organization. The mission of CMOD is to accelerate the identification, validation and appropriate application of biomarkers in cardiovascular and related diseases. The broad goal of CMOD is to create efficiencies toward improved patient healthcare.

Upcoming Events:

7th Annual CMOD Biomarkers and Surrogate Endpoints Symposium
“Streamlining to Promote Innovation and Efficiency”
October 19-21, 2009, Bethesda, Maryland

Organized in collaboration with representatives from the following organizations:

US Food and Drug Administration
National Institutes of Health
Center for Disease Control and Prevention
US Agency for Healthcare Research and Quality
Health Canada
Canadian Institutes for Health Research
Society of Nuclear Medicine
European Medicines Agency
and other public and private research organizations
www.cmod.org for more information

FACULTY

Peter Libby, Brigham and Women's Hospital

Peter Libby, MD, is the Chief of Cardiovascular Medicine at the Brigham and Women's Hospital in Boston, Massachusetts. He also serves as the Mallinckrodt Professor of Medicine at Harvard Medical School. Dr. Libby directs the D.W. Reynolds Cardiovascular Clinical Research Center at Harvard. His current major research focus is the role of inflammation in vascular diseases such as atherosclerosis. Dr. Libby has received numerous awards and recognitions for his research accomplishments, including the 2006 Distinguished Scientist Award of the American College of Cardiology. He is the co-founder of the International Partnership for Critical Markers of Disease.

Donald M. Black, GEHC Diagnostics

Donald Black, MD, MBA, is the head of Global Research and Development, Medical Diagnostics, GE Healthcare. Dr. Black received his Medical degree from the U of Michigan and completed his residency and fellowship at the U of Cincinnati, where he also studied business and law. Dr. Black joined GE Healthcare in November of 2004. Prior to joining GE, Dr. Black was VP of Global Strategic Development at Merck and Co. He was Vice President of Clinical Research at Parke-Davis/Warner-Lambert Co. (now part of Pfizer) from 1990 to 2000, where he was responsible for the clinical development of Lipitor as well as cardiovascular, renal, pulmonary and thrombotic research.

Michael Graham, University of Iowa College of Medicine

Michael Graham, PhD, MD, is Professor and Director of Nuclear Medicine at the U of Iowa College of Medicine. Dr. Graham is board certified in Internal Medicine and Nuclear Medicine. Dr. Graham received his bachelor's degree from MIT and his doctorate degree in Biophysics from the UC, Berkeley. Dr. Graham received his medical degree from the UCSF. He completed his residency in Internal Medicine and Nuclear Medicine at the U of Washington, where he was on the faculty for 19 years. He is currently Professor and Vice-chair of Radiology and Director of Nuclear Medicine at the U of Iowa. He is past chair of the American Board of Nuclear Medicine and is president-elect of SNM.

Dennis Swanson, University of Pittsburgh

Dennis Swanson holds a BS in Pharmacy and an MS in Nuclear Pharmacy. As a practicing nuclear pharmacist for over 20 years, he has been involved in the research and clinical application of imaging agents and in the regulations governing radioactive drug development. He has served on advisory committees to the U.S. FDA and Nuclear Regulatory Commission, and was the founding director of the U of Pittsburgh's Research Conduct and Compliance Office. Within this Office he has served in leadership positions as part of the Radiation Safety Committee, Radioactive Drug Research Committee, IRB Clinical Trials Office, and Office for Investigator-Sponsored IND and IDE Support.

Sally Schwarz, Washington University

Sally W. Schwarz, MS, BCNP, holds a BS in Pharmacy and a MS in Radiopharmacy. She is Board Certified in Nuclear Pharmacy (BCNP) by the American Pharmacist's Association (APhA) Board of Pharmaceutical Specialties. Ms. Schwarz is currently a Research Associate Professor at Washington U., Dpt. of Radiology and serves as the Director of Clinical PET Radiopharmaceutical production. She is the Secretary for the Radioactive Drug Research Committee for Washington Univ. Ms. Schwarz serves on the Nuclear Reg Commission Advisory Committee, the Medical Use of Isotopes (ACMUI), and the USP Radiopharmaceutical and Medical Imaging Expert Committee.

Eldon Leutzinger, Chemistry Team Leader, Medical Imaging, FDA

Eldon E. Leutzinger, Ph.D. in Chemistry from the University of Utah, joined FDA in 1989. Currently, in the Division of Pre-Marketing Assessment III & Manufacturing Science (Branch V), Office of New Drug Quality Assessment, his FDA career has been spent in the area of medical imaging drugs and radiopharmaceuticals, and liaison to the Division of Medical Imaging and Hematology Products. Scientific specialty and experience in radiochemistry and radiopharmaceuticals. Previous to joining FDA, he was in the Department of Nuclear Medicine, U of Connecticut Health Center, and Division of Biophysics (Department of Biophysical and Biochemical Sciences), School of Hygiene and Public Health, Johns Hopkins Medical Institutions.

Luke Augustine, PharmD, Cardinal Health

Luke Augustine received his Doctor of Pharmacy Degree from the University of Nebraska Medical Center in 1991 with additional training in the field of Nuclear Pharmacy completed at Purdue University, achieving his Board Certification in Nuclear Pharmacy in 1993. Luke Augustine has twenty plus years of Nuclear Pharmacy and PET manufacturing experience working in both Independent and Commercial settings. He has held a variety of positions of increasing responsibility for Cardinal Health ranging from Pharmacy Manager to VP/GM of the Southwest Region. His current role is VP of Business Development for the Nuclear Pharmacy Services division of Cardinal Health.

Joseph Hung, Mayo Clinic

Joseph C. Y. Hung, PhD, is Professor of Pharmacy and Professor of Radiology, Mayo Clinic College of Medicine, and director of Nuclear Pharmacy Lab and PET Radiochemistry Facility, Division of Nuclear Medicine (NM), Department of Radiology, Mayo Clinic. He holds a BS in pharmacy, and an MS and PhD in nuclear pharmacy. He is certified by the American Board of Science in NM in radiopharmaceuticals (RP) and radiochemistry, as well as a board certified nuclear pharmacist by the Board of Pharmaceutical Specialties. He has been an active member in many professional organizations and is the acting chair of the Expert Committee on RP and Imaging Agents, USP.

George Q. Mills, Perceptive Informatics

George Q. Mills, MD, MBA, is VP, Medical Imaging Consulting for Perceptive Informatics, a PAREXEL Company. He advises bio/pharmaceutical clients on the use of medical imaging for strategic decision-making and in support of regulatory submissions. As Division Director at the FDA, he was responsible for the review and approval of diagnostic and radiolabeled therapeutic drugs and biologics and was involved in the review of the Radioactive Drug Research Committee (RDRC) program, therapeutic and imaging Investigational New Drug Applications (INDs), Biologic License Applications (BLAs) and New Drug Applications (NDAs). His roles at FDA, including Branch Chief and designated Acting Deputy Division Director of CBER and CDER. Dr. Mills is certified by the American Board of Nuclear Medicine and the American Board of Pathology.