U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research | CDER
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Joint Presentations with Medicines & Healthcare products Regulatory Agency

Presenter & Facilitator Biographies

Ruben C. Ayala, Pharm.D.

Ruben is a Lead Pharmacologist in the Office of Study Integrity and Surveillance (OSIS) located in the Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER) at FDA. OSIS directs and conducts inspections of in-vivo and in-vitro bioavailability/bioequivalence studies and non-clinical studies submitted in support of pharmaceutical development, as part of the Agency's Bioresearch Monitoring (BIMO) program.

Before joining OSIS, Ruben was a reviewer in the Office of Clinical Pharmacology (OCP) at FDA. He reviewed drug applications for antiviral drugs including HIV, HCV, and other infections. Prior to joining FDA, Ruben obtained his post-doctorate training in clinical pharmacology at Hoffmann-La Roche, Doctorate Degree in Pharmacy from Western University of Health Sciences in California, and Bachelor of Sciences in Pharmacology from the University of California, Santa Barbara. He also held research positions including DMPK and Protein Formulation Pharmaceutics at Pfizer/Pharmacia and Amgen, respectively.

Kassa Ayalew, M.D., M.P.H.

Dr. Ayalew is a branch chief for the Good Clinical Practice Assessment Branch of the Division of Clinical Compliance Evaluation in the Office of Scientific Investigation in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). He oversees verification of the integrity of efficacy and safety data submitted to the FDA in support of new drug and biologic applications and the protection and assurance of the rights and welfare of human research subjects.

Dr. Ayalew obtained his M.D. from Haile Selassie University Medical Faculty in Addis Ababa, Ethiopia(also called Addis Ababa University Medical Faculty). He then worked as an assistant professor in the Department of Pediatrics at the Gondar University of Medical Sciences in Ethiopia and completed post-graduate training in pediatrics and child health at Leipzig University in Germany. He also

completed a pediatrics residency at the Long Island College of Hospital (State University of New York) followed by a fellowship program at Children's National Medical Center/George Washington University.

Dr. Ayalew is a Pediatrics Infectious Disease physician and holds an active license to practice medicine in Virginia. He serves as a pediatrician at Inova Fair Oaks Hospital where he provides clinical services in pediatrics and pediatric infectious diseases. He has given numerous didactic lectures and case presentations and has published article in peer review journals. He holds several awards and credentials from the FDA, where he has over 18 years of regulatory medicine and work experience.

Charles Bonapace, Pharm.D.

Dr. Bonapace is the Director of the Division of New Drug Bioequivalence Evaluation (DNDBE) in the Office of Study Integrity and Surveillance (OSIS), CDER. As the Director, he handles the GLP Team and two Bioequivalence Teams, which includes the conduct of inspections for GLP and BE studies, including Animal Rule studies, and communicating the findings and recommendations to the review divisions in the Office of New Drugs and Office of Generic Drugs.

Dr. Bonapace is the FDA representative to the Organisation for Economic Co-operation and Development (OECD) GLP Working Group (WG). He is a previous member of the FDA GLP WG responsible for modernizing the GLP regulations (21 CFR Part 58) governing the conduct of GLP studies and has contributed to the modernization of the Bioequivalence regulations (21 CFR part 320). He is a member of the Pathology Peer Review guidance WG, Animal Rule Compliance Program (CP) WG, In Vivo Bioequivalence Analytical and Clinical Site CP WGs, and In Vitro Bioequivalence Analytical Method WG. He takes part in the training of investigators in FDA's Office of Regulatory Affairs regarding the inspection of sites conducting nonclinical and in vivo bioequivalence studies.

Dr. Bonapace joined FDA/CDER in 2000 as a clinical pharmacology reviewer in the Division of Pharmaceutical Evaluation III in the Office of Clinical Pharmacology and supported the Division of Anti-Infective Drug Products. He became the Team Leader of the Anti-Infective Team in 2006. In 2010, he joined the Division of Scientific Investigations in the Office of Compliance supporting the Bioequivalence and Good Laboratory Practice Branch. Following the reorganization of the Office of Compliance, Dr. Bonapace became the Acting Team Leader of the GLP Team in 2011, Acting GLP Branch Chief in 2012, and GLP Branch Chief in 2014. Following the re-organization of the Office of Scientific Investigations, Dr. Bonapace became the Acting Director of DNDBE/OSIS in January 2015 followed by the Director in June 2015.

David Burrow, Pharm.D., J.D.

David Burrow currently serves as the Director of the Office of Scientific Investigations (OSI), within the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Compliance (OC). In this role, he leads efforts to protect the public from unsafe and ineffective drug products by managing the effective administration of 14 compliance programs (both pre- and post-market). Specifically, he leads the development and implementation of policies, surveillance activities, and compliance strategies, as well as enforcement of clinical and non-clinical drug product studies, bioequivalence studies, human subject protections, post-market Adverse Drug

Experience reporting requirements, Risk Evaluation and Mitigation Strategies, and Post Marketing Requirements. Dr. Burrow's oversight in each of these critical programs strives to guard the safety and efficacy data submitted to CDER and protect the rights, safety, and welfare of the American public by ensuring that all administrative, advisory, and enforcement actions taken by the office comply with all applicable laws and regulations, have adequate evidentiary support, and are consistent with Agency policy.

Dr. Burrow has held a variety of leadership positions during his seven years in OSI. For example; he served as the Deputy Office Director, Policy Staff Director, Associate Director for Policy and Communication, Enforcement Policy Team Leader, and Regulatory Counsel. Before joining the CDER, Office of Compliance, Dr. Burrow served with the Center for Devices and Radiological Health (CDRH) in their Office of Compliance. While in CDRH, he was responsible for the review of establishment inspection reports, assessment of industry complaints, review of advertising and promotion material, and drafting all types of regulatory correspondence, including; Warning Letters, Untitled Letters, Application Integrity Policy letters.

Dr. Burrow holds a Doctorate of Pharmacy from Duquesne University, and a Juris Doctorate from Widener University School of Law. He is licensed to practice law in the State of Maryland.

Seongeun (Julia) Cho, Ph.D.

Dr. Seongeun Julia Cho is the Director of the Division of Generic Drug Bioequivalence Evaluation (DGDBE)/Office of Study Integrity and Surveillance (OSIS) in CDER/FDA. DGDBE provides an oversight to bioequivalence/bioavailability studies submitted to FDA in support of new and generic drug applications through on-site inspections and compliance evaluations. Dr. Cho received a Ph.D. in Pharmacology from the Ohio State University and the postdoctoral fellowship at the University of Chicago Children's Hospital. She then worked at Wyeth Research/Pfizer as a principal investigator for ten years before she joined FDA. She served as a reviewer in the Office of Clinical Pharmacology, and then as a reviewer and a team lead in the Office of Scientific Investigations (OSI) in the Office of Compliance. During her tenure in OSI and OSIS later, she was involved in numerous projects and initiatives, including Generic Drug User Fee Act (GDUFA) implementations, guidance development, inspectional questionnaire pilot, enforcement activities, and international collaborations. Currently she leads the division's efforts on surveillance inspections, business process improvements, development of inspectional guides and compliance policy, and internal and external outreach activities.

Arindam Dasgupta, Ph.D.

Dr. Dasgupta is currently the Deputy Director of the Division of New Drug Bioequivalence Evaluation (DNDBE) in the Office of Study Integrity and Surveillance (OSIS) located in the Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER) at FDA. OSIS directs and conducts inspections of in-vivo and in-vitro bioavailability/bioequivalence studies and non-clinical studies submitted in support of pharmaceutical development, as part of the Agency's Bioresearch Monitoring (BIMO) program. Before joining OSIS, Dr. Dasgupta completed postdoctoral fellowships at Department of Biochemistry and Molecular Genetics, University of Virginia and National Cancer institute (NCI) at National Institutes of Health (NIH). After completing his fellowship, Arindam joined

the Center for Drug Evaluation and Research in 2008 as a Pharmacologist in the Division of Scientific Investigations, GLP and BE Investigations Branch. He served as acting Team Lead and lead Pharmacologist positions before talking up the current position of Deputy Director position. He has authored numerous scientific publications in prestigious peer-reviewed journals. Dr. Dasgupta's expertise are in the area of Pharmacology, Biochemistry and Molecular Biology. He has conducted inspections of several bioanalytical laboratories during his tenure in OSI and OSIS.

Andy Fisher, Lead Senior GCP Inspector, MHRA

Andy has a BSc (Hons) in Biology and a MSc in Medical Statistics and IT.

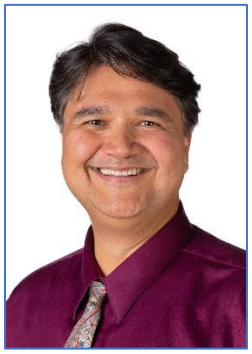
Andy worked as a Medical Statistician after gaining his MSc, being involved primarily in clinical trial design and data analysis. Andy also undertook some data management activities. After 3 years in this role, Andy moved into clinical research and became a Clinical Research Associate (CRA) at the start of 1996 and progressed to be a Clinical Project Manager. During these 7 years Andy was involved in a broad range of clinical trial activities for trials of pharmaceuticals and medical devices. Andy also had a part time role during his time as a CRA as an ISO9001 internal auditor. Andy's last 2 years in industry prior to joining the MHRA were spent as Compliance and Training Manager within clinical research.

Andy has been with the MHRA GCP Inspectorate since August 2005 and has inspected numerous commercial and non-commercial organisations, contract research organisations, eSystems vendors, phase 1 clinical units and investigator sites as part of the MHRA and EMA inspections. Andy also conducts inspections of phase 1 unit as part of the voluntary phase 1 accreditation scheme. Andy was part of the authoring team for the MHRA GCP Guide. Andy also continues to work with EU GCP inspector colleagues in the EMA GCP Inspectors Working Group sub-groups on Quality Risk Management, TMFs and Source Data that were responsible for the respective EU reflection papers and guidance documents.

Gail Francis, Expert GCP Inspector, MHRA

Gail Francis joined the MHRA in November 2003 as a GCP Inspector. Prior to joining the MHRA, Gail spent approximately 10 years in the Pharmaceutical industry. Her first role in the Pharmaceutical Industry was in Pharmacovigilance, before moving into Clinical Research and has held various positions in monitoring, Project Management, and more recently in GCP Compliance and Training Management. Gail was promoted to Senior Inspector in October 2005 and accredited to perform Pharmacovigilance Inspections in November 2007. In June 2010 Gail was promoted to Expert Inspector, GCP.

Sean Y. Kassim, PhD



Dr. Kassim is the director of the Office of Study Integrity and Surveillance (OSIS) in the Office of Translational Sciences (OTS) in FDA's Center for Drugs (CDER). OSIS oversees bioequivalence and bioavailability studies and non-clinical laboratories in support of pharmaceutical development, as part of the Agency's Bioresearch Monitoring (BIMO) program.

Previously, Sean was the director of the Office of Scientific Investigations (OSI), in CDER's Office of Compliance, overseeing compliance programs and enforcement for pharmaceutical BIMO (GCP, IRB) and post-market reporting (PADE, REMS, PMR) activities. In OSI, he also served as Deputy Office Director; Associate Director for Policy and Communication; acting Associate Director for Risk Science, Intelligence, and Prioritization; and team leader for the Informatics and Infrastructure Team. He started at FDA as a reviewer for the bioequivalence and GLP compliance program in OSI's predecessor, the Division of Scientific Investigations.

Before coming to FDA, Sean worked at the University of Washington in Seattle, using proteomic and genomic approaches to identify novel proteinase targets, identifying biomarkers for heart disease, and evaluating pulmonary anti-bacterial defenses. Sean received his doctorate from Washington University in St. Louis and his undergraduate degree from the University of Maryland Baltimore County.

Ni A. Khin, M.D.

Ni A. Khin is Director of Division of Clinical Compliance Evaluation, within Office of Scientific Investigations (OSI), Office of Compliance, Center for Drug Evaluation and Research, at FDA. In this position, she provides scientific oversight for CDER-assigned bioresearch monitoring (BIMO) activities including compliance programs of clinical investigators, sponsors and contract research organizations. She also leads OSI's international collaboration with global regulatory counterparts in good clinical practice (GCP) initiatives.

Prior to this position, Dr. Khin served as Medical Team Leader in the Division of Psychiatry Products, Office of New Drugs, where she oversaw the review of clinical protocols submitted under investigational new drug applications (INDs) for all phases of drug development. She also managed clinical reviews of New Drug Applications (NDAs) for all psychiatric indications. Dr. Khin joined the Agency in 2001 as a Clinical Reviewer in the Division of Neuropharmacologic Drug Products. She also served as Medical Officer and Branch Chief of GCP Branch 1, Division of Scientific Investigations. She conducted data-audit and for-cause inspections of clinical trial sites both in the US and abroad. Prior to coming to FDA, Dr. Khin was a Senior Staff Fellow in the Geriatric Psychiatry Branch at the National Institute of Mental Health.

Dr. Khin received her medical degree from the Institute of Medicine I, Rangoon, Burma (Myanmar). She completed residency training in Psychiatry at the State University of New York, Buffalo. She is board-certified in Psychiatry by the American Board of Psychiatry and Neurology. She also received a Master of Science Degree in Microbiology from Arizona State University. Her research interest includes trial design and methodology to improve detection of efficacy signals as well as regulatory and scientific issues regarding use of non-US data from multi-regional clinical trials in support of NDAs in the US.

Cynthia F. Kleppinger, M.D.

Cynthia Kleppinger, M.D. is currently a Senior Medical Officer in the Good Clinical Practice Assessment Branch, Division of Clinical Compliance Evaluation, Office of Scientific Investigations, Center for Drug Evaluation and Research at the US Food and Drug Administration. In this capacity, she directs, and may participate in, onsite inspections of clinical investigators, sponsors, monitors, and contract research organizations in collaboration with FDA's field organization.

Since joining CDER in 2008, Dr. Kleppinger has also held the positions of Team Leader for the Policy and Planning Team and Team Leader for International Policy in the Office of Scientific Investigations. Work included launching and then overseeing the collaborative FDA-European Medicines Agency Good Clinical Practice Initiative.

Prior to her work at CDER, Dr. Kleppinger was a Clinical Reviewer for 4 years in the Division of Vaccines and Related Products Applications, Center for Biologics Evaluation and Research/FDA. She also spent 3 ½ years at Science Applications International Corporation-Frederick, overseeing clinical trials as Director of the Clinical Safety Office in the Division of Intramural Research at the National Institute of Allergy and Infectious Diseases/National Institutes of Health.

Preceding that job, she was a Senior Medical Officer and Project Coordinator in the Center for the Clinical Trials Network at the National Institute on Drug Abuse at the NIH. She also has over 16 years as an active practicing clinician in academia, private practice, family and emergency medicine.

Phillip Kronstein, M.D

Phillip Kronstein, M.D. is a Team Leader for the Good Clinical Practice (GCP) Assessment Branch in the Division of Clinical Compliance Evaluation (DCCE)/Office of Scientific Investigations (OSI) at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). In this position, Dr. Kronstein provides regulatory scientific oversight for CDER-assigned bioresearch monitoring (BIMO) activities as well as provides scientific and clinical oversight to GCP reviewers and FDA field investigators. He also served as medical officer and team leader for the GCP Compliance Oversight Branch in OSI/DCCE and evaluated GCP complaints regarding clinical investigators, sponsors, and CROs in their conduct of FDA regulated clinical trials. While at OSI, he has participated in a number of guidance working groups, including for Part 11, eConsent, and EHRs in clinical trials. He has also presented at DIA on mobile devices in clinical trials and at ISPE on regulatory expectations for electronic data in clinical investigations.

Dr. Kronstein was previously a Senior Medical Officer in the Division of Psychiatry Products (DPP), where he managed clinical reviews of Investigational New Drugs (INDs) and New Drug Applications (NDAs). While in DPP, he was the Division Data Standards Lead and helped to develop disease specific data standards for mood disorders and schizophrenia.

Prior to joining the FDA in January 2008, he was a Clinical Research Fellow in the Experimental Therapeutics and Pathophysiology Branch at the National Institute of Mental Health, where he conducted trials in treatment-resistant depression and bipolar disorder. He received a Bachelor's of Science in Chemistry from the University of Chicago in 1995 and a Doctor of Medicine from Tufts University School of Medicine in 2001. He completed his residency training in Psychiatry at the Johns Hopkins Hospital in June 2005.

Jean Mulinde, M.D.

Dr. Mulinde is currently the Senior Policy Advisor for the Division of Clinical Compliance Evaluation in the Office of Scientific Investigations, CDER, FDA. Prior to joining the Office of Scientific Investigations, she was a Clinical Team Leader in the Division of Anti-Infective Products in CDER's Office of New Drugs. She received her M.D. and completed a residency in Internal Medicine at the University of South Alabama School of Medicine, and then completed a fellowship in Infectious Diseases at the University Of Maryland School Of Medicine. Before joining the FDA, she served as Assistant Professor of Medicine in the Division of Infectious Diseases, Program of Traumatology, at the University of Maryland's R. Adams Cowley Shock Trauma Center.

Robert Temple, M.D.

Dr. Robert Temple has been Deputy Center Director for Clinical Science at FDA's Center for Drug Evaluation and Research since 2009, participating in the direction of the Center's operations. He is also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I). ODE-I is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr. Temple served as Director, Office of Medical Policy from 1999-2009. The Office of Medical Policy is responsible for regulation of promotion through the Office of Prescription Drug Products (formerly, Division of Drug Marketing, Advertising, and Communication) and for assessing quality of clinical trials. Dr. Temple has a long-standing interest in the design and conduct of clinical trials and has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control and non-inferiority trials, trials to evaluate dose-response, and trials using "enrichment" designs.

Stephen Vinter, BSc (hons) CChem MRSC MCQI CQP

Stephen Vinter is Operations Manager for the GLPMA and Laboratories Group for the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. Prior to joining the Agency in 2012, Stephen worked in Operations Management at a Contract Research Organisation. Stephen has also worked in the manufacturing sector and is a Chartered Chemist and Chartered Quality Professional.

In his role as an Inspector, Stephen conducts GCP and GLP inspections of commercial organisations and laboratories in the UK and overseas, including the MHRA inspection programme for organisations conducting Bioequivalence studies.