**SPEAKER BIOGRAPHIES**

**Day 1: Tuesday, February 13, 2024**

**Patrizia Cavazzoni, MD**

*Director*
Center for Drug Evaluation & Research (CDER)
U.S. Food and Drug Administration (FDA)

Patrizia Cavazzoni, M.D., is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). The Center's mission is to ensure that safe, effective, and high-quality drugs are available to the public. To achieve this, CDER regulates the medical products under its jurisdiction throughout their lifecycle, oversees the development of new and generic drugs, evaluates applications to determine whether drugs should be approved, monitors the safety of drugs after they are marketed, conducts research to advance regulatory science and takes enforcement actions to protect the public from harmful products. Dr. Cavazzoni joined the FDA in January 2018 as CDER's Deputy Director for Operations where she has led several key initiatives on behalf of the organization. She also served as Acting Principal Deputy Commissioner of Food and Drugs from January 2019 to February 2019.

Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa. During her training, she was an investigator in clinical trials of novel antipsychotic and antidepressant medications and became a research collaborator within the International Group for The Study of Lithium Treated Patients. She subsequently received a full-time appointment to the Faculty of Medicine at the University of Ottawa and joined the Mood Disorders Program at the Royal Ottawa Hospital, where she treated patients suffering from severe mood disorders, taught students and conducted research on genetic predictors of bipolar disorder as part of a multidisciplinary international collaborative effort, authoring numerous peer-reviewed scientific publications.

After her tenure in academic medicine, Dr. Cavazzoni worked in the pharmaceutical industry for several years and held senior executive positions in clinical development, regulatory affairs, and safety risk management in large companies across multiple therapeutic areas, until she joined the FDA.

Dr. Cavazzoni obtained certification by the American Board of Neurology and Psychiatry in 1997 and 2008 and was a fellow of the Canadian Royal College of Physicians and Surgeons from 1997 until 2023. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists' Laughlin Fellowship.

Brenda Stodart, PharmD, MS, BCGP, RAC
*Captain* | United States Public Health Service (USPHS)
*Director* | Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER) | US FDA

CAPT Brenda Stodart is currently the Director for the Center for Drug Evaluation and Research's (CDER's) Small Business and Industry Assistance (SBIA) Program. Prior to her current position, CAPT Stodart was a Senior Regulatory Management Officer in the Office of Regulatory Policy (ORP). Before ORP, CAPT Stodart served as a Senior Health Promotion Officer in the Division of Drug Information for nine years. CAPT Stodart received her MS in Regulatory Science from University of Maryland, PharmD from the University of Arkansas Medical Sciences and BS in Pharmacy from Howard University. She is also a Board-Certified Geriatric Pharmacist (BCGP). CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

**Kassa Ayalew, MD, MPH**
*Division Director*
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI), Office of Compliance (OC)
CDER | US FDA

Kassa Ayalew is Division Director for the Division of Clinical Compliance Evaluation in the Office of Scientific Investigation at Center for Drug Evaluation and Research (CDER) in FDA. Dr. Ayalew 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 received his M.D. in 1989 from Haile Selassie University Medical Faculty in Addis Ababa, Ethiopia. Following graduation, he worked as an Assistant Professor in the Department of Pediatrics at the Gondar University of Medical Sciences in Ethiopia. After awarded a scholarship, he completed post-graduate training in pediatrics and child health at Leipzig University in Germany. Following successful completion of his post-graduate residency training at Leipzig University, he also completed pediatrics residency at the Long Island College of Hospital followed by a fellowship program at Children's National Medical Center/ George Washington University where he also obtained an MPH in public health. Dr. Ayalew holds an active license to practice medicine in State of Virginia. He is board certified in Pediatrics and Infectious Disease.

Dr. Ayalew works at Patient First Primary and Urgent Care in Virginia where he provides clinical services to both pediatrics and adult patients. He has given numerous didactic lectures, case presentations and published publications in peer review journals. He has decades of clinical and regulatory work experience.

**Leigh Marcus, MD**
*Senior Physician*
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI), Office of Compliance (OC)
CDER | US FDA

Dr. Marcus received her medical degree from the Medical College of Virginia/Virginia Commonwealth University and a Bachelor of Science from the University of North Carolina at Chapel Hill. She received specialty training as a resident in pediatrics at Yale University followed by subspecialty fellowship training in pediatric hematology and oncology at the Johns Hopkins Hospital and the National Institutes of Health National Cancer Institute (NIH-NCI). She received additional training in clinical trials research at the Duke University-NIH Program.

Following completion of her fellowship, Dr. Marcus stayed on at NIH-NCI for a research fellowship where she wrote and conducted successful clinical trials, one of which she published in the New England Journal of Medicine. She then took a faculty position as assistant professor at the George Washington University School of Medicine, and as attending physician at the Center for Cancer and Blood Disorders at Children's National Medical Center before joining the U.S. Food and Drug Administration in 2014 as a medical officer. Dr. Marcus was a clinical reviewer in oncology for 9 years and helped establish the new paradigm of tissue agnostic approvals. She reviewed high profile drugs including pembrolizumab for MSI/dMMR cancers and tissue mutation burden high (TMB) solid tumors, larotrectinib, and entrectinib for *NTRK*-fusion solid tumors. She transitioned to the good clinical practice assessment branch in 2022 as senior physician.

Dr. Marcus has been an invited speaker at various venues including the FDA, European Medicines Agency (EMA), American Association for Clinical Research (AACR), American Society of Clinical Oncology (ASCO), Children's Oncology Group (COG), Therapeutic Advances in Childhood Leukemia and Lymphoma (TACL) International Conference, The Emirates Hematology International Conference, and Accelerating Anticancer Agent Development (AAADV) workshop annually. She has board certification/subspecialty certification in pediatrics and pediatric hematology/oncology

**Hocine Abid, MD, MBA**
*National Manager*
Clinical Trial Compliance Program (CTCP)
Health Canada (HC)

Dr. Hocine Abid is an international medical doctor graduate. Hocine also holds an MBA from HEC Montréal and a Graduate Diploma in public administration from École Nationale d'Administration Publique (ENAP). Dr. Hocine Abid is currently the national manager for Health Canada's Clinical Trial Compliance Program that oversees the inspection of clinical trials. Before this, Hocine occupied different roles within Health Canada such as the manager of the good manufacturing practices inspection program, the Inspectorate regional manager for Ontario, overseeing Health Products Compliance and Enforcement programs, head of the medical cannabis program overseeing the evaluation and the delivery of authorizations to possess and produce cannabis for medical purposes. Hocine represented Health Canada on international symposium/inspections and delivered numerous presentations to industry/stakeholders.

**Andrew Fisher, BSc (Hons) in Biology and a MSc in Medical Statistics and IT**
*Lead Senior GCP INSPECTOR*
Medicines and Healthcare Products Regulatory Agency (MHRA)

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 worked 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. Andy has been a member of the ICH E6 (R3) Good Clinical Practice EWG since October 2020.

**Debbi Fox, BSc**
*Regulatory Compliance and Enforcement Specialist*, Health Canada

Debbi has a BSc. with a major in Biochemistry. Since joining Health Canada in 2007 she has worked as a Regulatory Compliance and Enforcement specialist in both the Good manufacturing and good clinical practices inspection programs within Health Canada. Debbi currently conducts clinical trial inspections across Canada and has also conducted international inspections in support of Health Canada's mandate. Prior to joining Health Canada, Debbi worked in the pharmaceutical industry in various areas including Assay Development, Product Development and Quality Assurance Validation. She represented Health Canada on international symposium/inspections and delivered numerous presentations to industry/stakeholders.

**Elena Boley, MD, MBA**
*Senior Physician*
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI), Office of Compliance (OC)
CDER | US FDA

Dr. Boley is a senior physician in the Good Clinical Practice Assessment Branch of the Office of Scientific Investigations in the Center for Drug Evaluation and Research (CDER) at FDA, where she consults for the Division of Antivirals and the Division of Psychiatry. For the previous six years, she served as a clinical reviewer in the Division of Urology, Obstetrics & Gynecology in the Office of New Drugs, also in CDER. In that position, she advised and regulated investigators and industry sponsors in their drug development programs to ensure the safety of human subjects in clinical trials and to encourage trial design resulting in useful and meaningful efficacy and safety data. Additionally, she reviewed new drug applications to determine if the data submitted supported safety, efficacy, and an acceptable benefit/risk profile for the proposed new drug.

Prior to joining the FDA, Dr. Boley practiced internal medicine for 16 years, primarily at the faculty practice of The George Washington School of Medicine and Health Sciences, where she also instructed medical students in the clinic and the classroom. Additionally, she served as a physician leader for health care quality initiatives, a senior policy advisor in GW's Center for Healthcare Quality, and the Director of Executive Health Services. She continues to hold a faculty appointment as an Associate Clinical Professor of Medicine and is a coach for medical students as they develop their professional and personal identities as physicians, life-long learners, and excellent communicators.

Dr. Boley received her BA in Neuroscience from Amherst College and her MD from the Duke University School of Medicine. She completed her residency in Internal Medicine at Mount Sinai Medical Center in New York City and subsequently earned her MBA from the Carey School of Business at Johns Hopkins University. She is a diplomate of the American Board of Internal Medicine.

**Mandy Budwal-Jagait, MSc**
*Head of GCP and Lead Senior GCP Inspector*
Medicines and Healthcare Products Regulatory Agency (MHRA)

Mandy Budwal-Jagait is the Head of GCP at the Medicines and Healthcare Products Regulatory Agency (MHRA). She is responsible for the MHRA GCP Inspection Programme and is also a Lead Senior GCP Inspector. Mandy has worked in the MHRA as an inspector since 2014 and during this time was also Head of the pharmacovigilance inspection team for 2 years.

Prior to joining the Agency, Mandy has held Clinical Research and Quality Assurance roles in the Pharmaceutical Industry. She holds a MSc in Toxicology and BSc (Hons) in Medical Biochemistry

**Karen Bleich, MD**
*Lead Physician*
Office of Medical Policy (OMP)
CDER | US FDA

Karen Bleich is a Lead Physician in the Office of Medical Policy in FDA's Center for Drug Evaluation and Research (CDER). She has been at the FDA since 2016, with additional roles in CDER's Office of New Drugs and Office of Scientific Investigations. Before joining the FDA, she was an Assistant Professor of Radiology at Johns Hopkins School of Medicine. Dr. Bleich earned her medical degree from Duke University and completed her postgraduate training at the University of Maryland and at Johns Hopkins.

**Hayley Dixey, BSc**
*Lead Senior GCP Inspector*
Medicines and Healthcare Products Regulatory Agency (MHRA)

Hayley has over 15-years' experience auditing and inspecting clinical trials in UK, India, China, America, and Brazil. Hayley joined the MHRA as a GCP Inspector in 2015 and has led inspections of some of the largest Pharmaceutical, CRO and Phase I companies. Hayley has inspected with numerous other regulators including FDA, EMA and ANVISA. Prior to joining the agency Hayley worked in Quality Assurance and Quality System roles in Commercial Phase I Clinical Trial Units. Hayley has a BSc Hons in Pharmacology.

**Alicja Kasina, MSc, BPharm**
*Senior Regulatory Advisor*
Regulatory Operations and Enforcement Branch (ROEB)
MDCCD | CCBO | CTCP | Health Canada

Alicja Kasina is a Senior Regulatory Advisor for Clinical Trials Compliance Program (CTCP), Health Canada. She joined the Public Service in 1996 where she has been active in several roles including Drug Inspector and Medical Devices Specialist for Health Canada. She has performed many clinical trial inspections in Canada and some in Europe under the umbrella of the Pharmaceutical Inspection Co-operation Scheme Joint Visits Programme. Alicja also participated as a mentor at APEC Advanced GCP Inspection Workshop in Asia. Alicja received a MSc in Molecular Biology from Jagiellonian University, Cracow, Poland and BPharm, Dalhousie University, Halifax Nova Scotia. She has worked over 15 years in medical research in the areas of endocrinology, immunology and microbiology and is a licensed pharmacist. She is a co-author of several research papers and has given several presentations on subjects related to regulatory matters concerning health products both domestically and internationally.

**Lee Pai-Scherf, MD**
*Senior Medical Officer*
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI), Office of Compliance (OC)
CDER | US FDA

Dr. Pai-Scherf is a reviewer in the Good Clinical Practice Assessment Branch of the Division of Clinical Compliance Evaluation (DCCE) /Office of Scientific Investigations (OSI) in CDER/FDA. She provides regulatory and scientific oversight for CDER-assigned bioresearch monitoring activities and scientific and clinical oversight to FDA field investigators. She is a medical oncologist and

serves as a subject matter expert in GCP inspections to evaluate data integrity, quality, and safety of human subjects in clinical trials.

**Shila Rastegar, MSc**
*Regulatory Compliance and Enforcement Specialist*
CTCP, Regulatory Operations and Enforcement Branch
Health Canada

Ms. Shila Rastegar has a Master's degree in Biochemistry from the University of Ottawa, Canada, and she has twenty-five years of experience working with Health Canada in different divisions. Ms. Rastegar is currently a Regulatory Compliance and Enforcement specialist in the Clinical Trial Compliance Program of the Regulatory Operations and Enforcement Branch. Since 2008, she is conducting inspections of clinical trials for compliance with Canadian regulations, at sponsors, Contract Research Organization and Investigator sites. She is actively contributing to the development of the policies and guidance documents for the program. Prior to that, she was with the Medical Devices Unit conducting regulatory inspections of manufacturers, importers and distributors of medical devices in Canada. Shila represented Health Canada on international symposium/inspections and delivered numerous presentations to industry/stakeholders.

**Cheryl Grandinetti, PharmD**
Clinical Pharmacologist
Good Clinical Practice Assessment Branch (GCAB)
Division of Clinical Compliance Evaluation
Office of Scientific Investigations
CDER | US FDA

Dr Grandinetti is a reviewer in the Good Clinical Practice Assessment Branch (GCAB) of the Division of Clinical Compliance Evaluation /Office of Scientific Investigations in CDER/FDA. She provides regulatory and scientific oversight for CDER-assigned bioresearch monitoring activities and scientific and clinical oversight to FDA field investigators. She serves as a subject matter expert in GCP inspections to evaluate data integrity, quality, and safety of human subjects in clinical trials.

**Regina Zopf, MD**
*Senior Medical Officer*
Office of Scientific Investigations
CDER | US FDA

Dr. Regina Zopf is a Senior Physician in the Good Clinical Practice Assessment Branch of the Division of Clinical Compliance Evaluation /Office of Scientific Investigations in CDER/FDA. She provides regulatory and scientific oversight for CDER-assigned bioresearch monitoring inspections and scientific and clinical oversight to FDA field investigators. She is an Obstetrician Gynecologist and serves as a subject matter expert in GCP inspections evaluating data integrity, trial quality, and the safety of human subjects in clinical trials. Prior to joining OSI, she was a medical officer in the Division of Urology, Obstetrics and Gynecology products in CDER/FDA where she reviewed numerous investigational new drug applications and marketing applications in obstetrics and gynecology and has served on various FDA bioinformatics committees and work groups. She was also an active member of PhUSE and published on the use of FHIR in the generation of Real World Evidence. Before joining the FDA, Dr. Zopf was a Clinical Investigator in HIV trials in obstetrics and gynecology through the IMPAACT Network through Children's Hospital and Washington Hospital Center study sites. Dr. Zopf completed her residency in Obstetrics and Gynecology as well as her Medical Degree at the George Washington University School of Medicine and Health Sciences in Washington, D.C. and a Master's in Public Health at Columbia University in New York City.

**Alex Basiji, MSc**
*Director*
ROEB, Health Canada (HC)

Alex has an educational background in Environmental Sciences. He holds a BSc/MSc. in Climate Change Science. Alex has been a federal public servant for 26 years in Canada. He has been Health Canada's National Director of Clinical Compliance and Border Operations for the last 7 years. In his current capacity he has been responsible for providing executive leadership in supporting, influencing regulatory program priorities including the delivery of large and complex national operations, namely clinical trial and biological products compliance as well as the importation of health products at the Canadian border ports of entry. Under Alex's leadership, important efforts are centered presently on modernizing the activities of the national Clinical Trial Compliance Program, ensuring that the transformation of the program adopts a robust risk-based approach and that the program is aligned with other foreign regulatory agencies. Alex is well known as a dedicated triathlete.

**DAY 2: Wednesday, February 14, 2024**

**James Pound, BSc (Hons) CChem**
*Deputy Director*
Standards and Compliance
Medicines and Healthcare Products Regulatory Agency (MHRA)

James Pound joined the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) in 2008. He has worked in a variety of roles within the MHRA and is a senior leader within the Agency with responsibility for our medicines GXP compliance teams, the British Pharmacopoeia, Agency physico-chemical laboratory and medical devices approved body audit, proactive market surveillance and compliance.

He holds an honours degree in Chemistry and has previously worked in a variety of roles focused on analytical chemistry for both multinational pharmaceutical manufacturers and independent UK analytical laboratories.

**Adil Nashed, B.V.Sc., D.H.M.S**
*Good Clinical Practices Compliance Specialist*
Health Canada

Adil Nashed graduated as a Veterinarian from the University of Khartoum, Sudan. He successfully completed his Veterinary Internship in Vienna, Austria under the supervision of the University of Vienna. Adil also holds a postgraduate diploma in Homeopathic Medicine and Science from the Homeopathic College of Canada. Adil has been a Regulatory Compliance and Enforcement specialist with the Federal Government of Canada for over 25 years. Adil has been since 2005 a Good Clinical Practices Compliance Specialist with Health Canada where he conducts inspections of clinical trials under the Canadian Regulations. Adil was actively involved in the specialized training of new inspectors in the Clinical Trial Compliance Program and was also involved in designing training modules for the program. Adil represented Health Canada on international symposium/inspections and delivered numerous presentations to industry/stakeholders.

**Barbara Wright**
*Foreign Cadre Director* | Foreign Inspection Cadre
Office of Bioresearch Monitoring Operations (OBIMO)
Office of Regulatory Affairs (ORA) | US FDA

Barbara Wright currently serves as the Supervisor of the Foreign Inspection Cadre within FDA's Office of Bioresearch Monitoring Operations. She is responsible for the assignment and oversight of international inspections covering BA/BE, GCP, GLP, and PV compliance programs. Barbara was selected for this position at the formation of the cadre in 2018. She has over 30 years' experience as a field investigator and has conducted inspections, both domestically and internationally, in the full range of FDA regulated products. Ms. Wright has been serving as a course advisor and instructor for FDA's Office of Training, Education and Development since 2002, providing training in clinical bioresearch monitoring and data integrity inspections to FDA field investigators, Center personnel, and representatives of foreign governments. She holds a certificate in Clinical Trials Management from the University of Chicago, a bachelor's degree from Southeastern Louisiana University, and FDA certification in Clinical Bioresearch Monitoring.

**Jason Wakelin-Smith, BSc., PTQA**
*Expert GCP Inspector and Head of the Compliance Expert Circle*
Medicines and Healthcare Products Regulatory Agency (MHRA)

Jason joined the MHRA in November 2006 as a GCP Inspector, became a Senior Inspector in 2015, Lead Senior Inspector in 2017 and Expert GCP Inspector and Head of the Compliance Expert Circle in April 2022.
Jason previously had a split role (2011-2022) between the GCP and laboratories inspection teams within the MHRA conducting a variety of inspections including GCP inspections of sponsors, CROs and analytical laboratories, bioequivalence trials and GLP inspections. Since becoming an Expert Inspector Jason continues to conduct GCP inspections, support the GCP team and provide technical input at both a national and international level. As Head of the Compliance Expert Circle Jason leads the MHRA's team of Expert Inspectors.

Jason has a BSc (hons) in Biomedical Science and a Postgraduate Diploma in Pharmaceutical Technology & Quality Assurance. Previously Jason worked in the UK National Health Service in hospital pharmacy (including clinical trials and manufacturing).

**LCDR Iram Hassan, PhD**
*Reviewer*, DCCE, GCOB
*Commissioned Corps Scientist Officer*, USPHS
CDER | US FDA

LCDR Iram Hassan is a U.S. Public Health Service (USPHS) Commissioned Corps Scientist Officer and has been with the FDA for about 15 years. She currently serves as a Reviewer at FDA Center for Drug Evaluation and Research (CDER), Office of Compliance, Office of Scientific Investigations. Prior to her current position, she served as a Supervisory Consumer Safety Officer in FDA Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations and as a Bioresearch Monitoring (BIMO) Specialist in ORA Office of BIMO Operations. Over the course of her FDA career, she has conducted inspections in various program areas including BIMO, Pharma, Biologics, Medical Devices, and Foods including dietary supplements. LCDR Hassan has three years of pharmaceutical industry prior to joining the FDA and received her doctorate degree in Pharmacology from New York Medical College.

**Richard Berning**
*Foreign BIMO Cadre*
Office of Bioresearch Monitoring (OBIMO)
Office of Regulatory Affairs (ORA)
US FDA

Mr. Berning has over 13 years of experience as an investigator with US FDA and has served on the Office of Bioresearch Monitoring's International Inspection Cadre since its inception in 2018. He has conducted international inspections and remote regulatory assessments throughout the onset and abatement of the COVID-19 pandemic and has ground-level, firsthand experience of the changes to the conduct and assessment of clinical trials across many countries over this timespan.

**Jason Wakelin-Smith**
*Expert GCP Inspector and Head of the Compliance Expert Circle*
MHRA

*(see biography above)*

**Jennifer Evans, BSc**
*Compliance Specialist*
ROEB | Health Canada

Jennifer Evans obtained her degree in Biochemistry from the University of Victoria, in British Columbia, Canada. She worked in the pharmaceutical and biotechnology industries in research, clinical and quality roles for 14 years prior to joining Health Canada in 2012 as a Regulatory Compliance and Enforcement specialist in support of Canada's national compliance and enforcement program for clinical trials. As a compliance specialist with the Clinical Trial Compliance Program, Jennifer has been involved with numerous inspections of qualified investigators, sponsors and contract research organizations. Jennifer delivered numerous presentations to Canadian industry/stakeholders.

**Jenn Sellers, MD, PhD**
*Branch Chief*
Good Clinical Practice Assessment Branch
DCCE, OSI, OC
CDER | US FDA

Dr. Sellers is Branch Chief of GCP Assessment Branch. She is board certified pediatrician who also holds a Ph.D. in Computational Biology. She has been with the US FDA in the past 15 years and with GCP Assessment Branch in the Office of Scientific Investigations for over 9 years.

**LCDR Jennifer Adams, MPH**
*Foreign Cadre Director*
*LCDR*, USPHS
Office of Bioresearch Monitoring (OBIMO)
Office of Regulatory Affairs (ORA)
US FDA

LCDR Adams has worked as a USFDA Investigator since 2010, including two years at the Agency's India Office in New Delhi. Her field work for USFDA has focused on OBIMO generally and Bioequivalence/Bioavailability in particular. Upon her return from India, she entered an international work planning position, where she planned all foreign operations for USFDA OBIMO for over three years, including the challenging times of the COVID-19 pandemic. Most recently, LCDR Adams has become a Foreign Cadre Director, supervising a team of dedicated foreign travelers for the Agency, and managing the foreign BIMO program. Before joining the USFDA, Jennifer worked for the University of Michigan Center for Global Health as a research associate in health policy. She has an MPH in Epidemiology and is a Commissioned Officer in the U.S. Public Health Service.

**Rachel Mead, BSc (Hons)**
*Senior GCP Inspector*
MHRA

Rachel joined the MHRA in July 2019 and conducts a variety of GCP routine and triggered inspections in commercial and non-commercial organizations, including Phase I units registered under the MHRA Phase I Accreditation Scheme. Prior to joining the Agency, Rachel was a Quality Manager at a global CRO having previously held a number of clinical monitoring roles at Pharmaceutical Companies for over 10 years.

Rachel has a BSc (Hons) in Pharmacology from the University of Manchester.

**Emily Gebbia, J.D.**
*Associate Director of Regulatory Development*
Office of Scientific Investigations
Office of Compliance
CDER | US FDA

Emily Gebbia is the Associate Director of Regulatory Development in the Office of Scientific Investigations (OSI) within the Office Compliance in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. In this role, Emily provides strategic leadership and subject matter expertise for OSI's policy efforts, including the development of regulations and guidance related to good clinical practice, human subject protection, postmarketing safety, and other bioresearch monitoring programs. She also has responsibility for legislative activities affecting OSI's programs and works on internal business process improvements and internal and external communications. She previously served in CDER's Office of New Drugs as the Policy Staff Director for Office of Therapeutic Biologics and Biosimilars and in the Office of Compliance as the Senior Advisor for Compounding Compliance and Enforcement. She first joined FDA in CDER's Office of Regulatory Policy as a Regulatory Counsel.

Prior to joining FDA, Emily was an attorney at Hogan Lovells, advising a range of health sector clients, primarily on Medicare and Medicaid and other healthcare regulatory issues, and a law clerk for the Hon. Richard C. Tallman of the Ninth Circuit Court of Appeals in Seattle, WA. Emily holds a Juris Doctorate from Catholic University of America, Columbus School of Law.

**Mandy Budwal-Jagait**
*Head of GCP and Lead Senior GCP Inspector*
MHRA
*(see biography above)*

**CDR LaKisha Williams, MSN, PMHNP-BC**
*GCP International Liaison*
*CDR* | USPHS
Office of Scientific Investigations (OSI)
Division of Clinical Compliance Evaluation (DCCE)
OC | CDER | US FDA

LaKisha Williams is a Commander (CDR) in the United States Public Health Service (USPHS), with over 15 years' experience with the FDA. She started her FDA career as an investigator within the Office of Regulatory Affairs, conducting inspections across the full range of FDA regulatory products. She moved to CDER and worked in several positions, from Consumer Safety Officer, Team Leader, Project Management Officer, and Regulatory Review Officer. CDR Williams currently serves as the GCP International Liaison within the Office of Scientific Investigations, Division of Clinical Compliance Evaluation (DCCE). CDR Williams has a Bachelor and Master of Science in Nursing and is a Board Certified Psychiatric Mental Health Nurse Practitioner.

Prior to joining FDA, CDR Williams worked as a Nurse in the US Army Nurse Corps. She served 9 years in the Army before joining the USPHS.

**Reza Salehzadeh, MSc**
National Inspection Supervisor, CTCP
Health Canada

Reza holds a master's degree in Organic Chemistry from York University, Canada. For 15 years, Reza worked in Health Canada's Good manufacturing practices inspection program as an inspector, specialist, supervisor then as acting manager. He is currently the National Inspection Supervisor within Health Canada's Clinical Trial Compliance Program. Prior to the government, he worked in the pharmaceutical industry as a research organic chemist for 5 years. Reza represented Health Canada on international symposium/inspections and delivered numerous presentations to industry/stakeholders. Outside of work, he enjoys playing tennis, skiing, and travelling the world.

**Ryan Raffaelli, MD**
*Lead Physician*
DCCE
Office of Scientific Investigations (OSI)
OC | CDER | US FDA

Dr. Raffaelli is a Lead Physician with the Good Clinical Practice Compliance Oversight Branch of the Office of Scientific Investigations (OSI) in FDA. He has held this role since 2020, having joined OSI as a reviewer in 2017. He oversees a team providing regulatory and scientific oversight of clinical trials to ensure the integrity of data and the safety of human subjects.

Prior to joining OSI and after beginning his career at FDA in 2009, Dr. Raffaelli had been a senior reviewer in what is now the Office of Nonprescription Drugs in the Office of New Drugs, CDER/FDA.

Dr. Raffaelli received his M.D. in 2002 from Thomas Jefferson University – Jefferson Medical College (Philadelphia, PA), completing a residency in general pediatrics at Children's Hospital at Montefiore (2006; Bronx, NY) and a fellowship in pediatric nephrology at Children's Hospital of Philadelphia (2009; Philadelphia, PA).

**Cheryl Grandinetti, PharmD**
*Pharmacologist* | OSI | FDA
*(see biography above)*

**DAY 3: Thursday, February 15, 2024**

**Seonguen Julia Cho, PhD**
*Division Director*
Division of Generic Drug Study Integrity (DGDSI)
Office of Study Integrity and Surveillance (OSIS)
CDER | US FDA

Dr. Seongeun Julia Cho is the Director of the Division of Generic Drug Study Integrity (DGDSI) in the Office of Study Integrity and Surveillance (OSIS) in CDER, FDA. She manages a program in the Office that oversees inspections and evaluation of bioavailability and bioequivalence studies and ensures that data submitted in support of new and generic drug applications are reliable and studies were conducted in compliance with the applicable FDA laws and regulations. In addition, Dr. Cho oversees the Office's international program to foster global harmonization and regulatory oversight.

**Sean Kassim, PhD**
*Office Director*
Office of Study Integrity and Surveillance (OSIS)
Office of Translational Sciences (OTS)
Center for Drug Evaluation and Research (CDER)/ US FDA

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 Drug Evaluation and Research (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.

**Stephen Vinter, BSc (Hons) CChem MRSC MCQI CQP**
Head of Compliance Team 1, MHRA

Stephen is Head of Compliance Team 1 at the MHRA which is responsible for the delivery of Good Clinical Practice, Good Pharmacovigilance Practice and Good Laboratory Practice inspections.

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 Stephen leads the compliance team to deliver inspections and new approaches to compliance activities. He has worked on several regulatory guidance documents and represented the Pharmaceutical Inspection Co-operation Scheme (PIC/S) as an observer on the ICH M10 Expert Working Group.

**Mei Ou**, Ph.D.
*Lead Pharmacokineticist*
Division of Generic Drug Study Integrity (DGDSI)
Office of Study Integrity and Surveillance (OSIS)
Office of Translational Sciences (OTS)
CDER | US FDA

Dr. Mei Ou is currently a Lead Pharmacokineticist in Division of Generic Drug Study Integrity (DGDSI), Office of Study Integrity and Surveillance (OSIS), Office of Translational Sciences (OTS). In this role, she leads one of teams in DGDSI by inspecting domestic and foreign analytical sites where data for in vitro and in vivo bioequivalence, bioavailability, pharmacokinetic, pharmacodynamic and clinical endpoint studies and by evaluating inspections of clinical sites conducted by the Office of Regulatory Affairs (ORA) and providing recommendations to the review divisions regarding data acceptability to support INDs, NDAs, BLAs and ANDAs.

Dr. Ou received her M.D./B.S. and M.S. degrees from Shanghai Medical College of Fudan University, China in 2004 and her Ph.D. degree in major of Pharmaceutics and Pharmaceutical Chemistry from University of Utah in 2009. After that, she joined the Pharmacokinetics, Pharmacodynamics and Drug Metabolism (PPDM) Department in Merck & Co. Inc. as a Sr. Scientist, where her work involved RNAi Therapeutics. In 2015, Dr. Ou joined FDA as a Biopharmaceutics Reviewer and served a Senior Pharmacologist in Division of Biopharmaceutics (DB), Office of New Drug Product (ONDP), Office of Pharmaceutical Quality (OPQ), supporting new and generic drug application review and approval. She also served as the Application Technical Lead (ATL) and Cross Discipline Team Leader (CDTL) for several NDAs under the Office of Oncology Diseases and has contributed to multiple working groups at FDA. Over the past 9 years in FDA, Dr. Ou has received numerous awards from FDA for her dedication and accomplishment as a scientist, reviewer, and leader.

**Michael McGuinness**
*Head of GLP & Laboratories*
MHRA

Michael is Head of GLP & Laboratories within the MHRA Compliance Team One and is Head of the United Kingdom Good Laboratory Practice Monitoring Authority. Michael joined the MHRA in 2015 as an Inspector within the laboratories inspection team having previously worked in a Quality Assurance (QA) organization. While in industry Michael worked with a range of organizations including GLP Test Facilities and also laboratories involved in the conduct of clinical trial sample analysis.

In his role Michael leads the team of inspectors who conduct GCP, GMP and GLP inspections of laboratories and test facilities within the UK and overseas including facilities as part of the MHRA inspection programme for organisations conducting Bioequivalence studies.

**Yiyue Cynthia Zhang, PhD, RAC**
*Senior Staff Fellow*
Office of Study Integrity and Surveillance
Office of Translational Sciences
CDER | US FDA

Dr. Yiyue (Cynthia) Zhang is currently a Senior Staff Fellow with Office of Study Integrity and Surveillance, Office of Translational Sciences, Center for Drug Evaluation and Research (CDER). Dr. Zhang has conducted, coordinated, and reviewed comprehensive FDA BIMO clinical and analytical inspections covering BA/BE, PK, PD, immunogenicity and animal rule studies in support of NDA, ANDA, BLA and IND applications.

Dr. Zhang has a Ph.D. in Cellular and Molecular Pharmacology and a B.S. in Pharmacy. She completed a postdoctoral fellowship at Johns Hopkins University School of Medicine prior to joining FDA.

**Doug Pham, JD, Pharm.D.**
*Associate Director* for Clinical Policy
Office of Study Integrity and Surveillance (OSIS)
CDER | US FDA

Doug Pham is the Associate Director for Clinical Policy in the Office of Study Integrity and Surveillance in the FDA's Center for Drug Evaluation and Research. He received a pharmacy degree from Oregon State University and his law degree from the University of Oregon. Doug recently joined OSIS after 10 years in CDER's Office of Compliance and is currently focused on developing and improving the clinical BA/BE inspection program.

**Emma Whale, Hons Biomedical Science**
Senior GCP/GLP Inspector
MHRA

Emma Whale is a Senior GCP & GLP Inspector for the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. Prior to joining the Agency in July 2008, Emma worked for eight years as a GLP Auditor and Deputy GLP Quality Manager with experience in both Sponsor Organisations and Contract Research Organisations. Emma has also worked in histopathology for a large agrochemical company and she has an honours degree in Biomedical Sciences.
In her role as a Senior Inspector, Emma conducts inspections of both GCP and GLP commercial and non-commercial organisations in the UK and overseas inspections of organisations conducting Bioequivalence studies.

**Carolyn Volpe, PharmD, MS**
*Team Leader*
Postmarketing Safety Branch
Division of Enforcement and Postmarketing Safety
Office of Scientific Investigations
US FDA

Carolyn Volpe is a licensed pharmacist and serves as the Team Leader for the Pharmacovigilance Compliance Team in FDA's Center of Drug Evaluation and Research Office of Compliance Office of Scientific Investigations. She has over 14 years' experience at FDA in post-marketing drug safety, including as a safety evaluator and as a Branch Chief for the Marketed Unapproved Drugs Program. Currently, she serves as an expert on post-marketing safety reporting requirements for drugs and therapeutic biologics marketed within the U.S. She received her PharmD from the University of Pittsburgh and Master of Science in Regulatory Science from the University of Maryland.

**Sherry Bous, PharmD**
*Director*
Division of Enforcement and Postmarketing Safety,
FDA Office of Scientific Investigations

Since April 2017, Sherry Bous has been director of the Division of Enforcement and Postmarketing Safety, part of the Office of Scientific Investigations in CDER's Office of Compliance.

Prior to that, she held various positions in the Office of Regulatory Affairs (ORA) including Branch Chief of the Dedicated Foreign Drug Cadre, Supervisory Investigator, and Level III Drug Investigator. She started her career in the US FDA in the Office of Generic Drugs as a Pharmacologist.

**Claire Longman, MSc**
Expert Pharmacovigilance Inspector, MHRA

Claire has over 15 years' experience working within Pharmacovigilance. She is currently the Expert Pharmacovigilance Inspector at the MHRA. She began her career in Industry in 2008 working in Pharmacovigilance and gained experience in multiple areas including case coding, quality control, authoring PBRERS, signal detection and evaluation processes. She then transitioned to be the Local Safety Officer for the UK and worked within medical information followed by a brief experience in the consultancy arena. Claire started at the MHRA in 2014 as a Pharmacovigilance Inspector where she has conducted over 100 GPvP inspections. Claire has progressed through roles as a Senior Pharmacovigilance Inspector and most recently covered maternity leave as Head of the GCP Compliance Team before taking on her current role. Claire has much experience in leading inspections, presenting at conferences, and inputting into regulatory legislation and guidance. Claire has an interest in global collaboration around PV inspections and has been involved in a variety of projects to encourage harmonisation including training of both from Inspectors from Europe and of African nations and is deputy chair on the GPvP PIC/S Working Committee for GVP Best Practice.

**Paul Baillargeon**
Regulatory Compliance and Enforcement Specialist
Health Canada

Paul Baillargeon is a chemist with 20 years' experience in the private pharmaceutical sector in various positions in QA/QC, Manufacturing and Clinical Supplies. He joined Health Canada in 2019 and has been a good pharmacovigilance practices (GVP) inspector ever since, participating in GVP inspections of the Canadian market authorization holders as well as joint GVP inspections with the European Medicines Agency. As inspector-specialist, Paul collaborates with other health authorities such as MHRA and FDA to improve the understanding of GVP in the modern era.

**Namita Kothary, PharmD, RAC (US)**
Associate Director for Scientific Affairs, Division of Enforcement and Postmarketing Safety
FDA Office of Scientific Investigations

Namita Kothary is a licensed pharmacist with hospital, pharmaceutical industry, and Food and Drug Administration (FDA) experience in medical information, pharmacovigilance, and compliance. As the Associate Director of Scientific Affairs within FDA's Center for Drug Evaluation and Research / Office of Compliance / Office of Scientific Investigations / Division of Enforcement and Postmarketing Safety (DEPS), Dr. Kothary develops and executes overall strategy for international collaborations and outreach for DEPS. Dr. Kothary also serves as a senior expert within DEPS on working groups related to DEPS programs, including postmarketing safety as well as compliance and enforcement actions for FDA's Bioresearch Monitoring program that covers prescription and nonprescription drugs and therapeutic biologics.

Dr. Kothary also held FDA positions as a: Consumer Safety Officer on the Pharmacovigilance Compliance Team, Branch Chief for the postmarketing safety compliance programs, and safety evaluator in pharmacovigilance. Prior to her roles in FDA, Namita served as a drug information specialist, clinical

pharmacist, and safety reviewer in the pharmaceutical industry. Dr. Kothary received her PharmD from Rutgers, the State University or New Jersey, completed a specialized residency in drug information, and holds a Regulatory Affairs Certification (US).

**Ginneh Stowe, MS**
*Health Scientist*, Oncology Operations Team
FDA Oncology Center of Excellence

Ginneh Stowe is a Health Scientist on the Oncology Operations Team within the U.S. Food and Drug Administration's Oncology Center of Excellence (OCE). She works in collaboration with OCE leadership to provide essential information related to regulatory issues and medical products to external stakeholders in the oncology community. During her tenure at FDA, Ms. Stowe has also worked in offices within the Center for Drug Evaluation and Research covering communication, postmarketing drug safety, and compliance.

Prior to working at FDA, Ms. Stowe held positions at Booz Allen Hamilton and Washington Hospital Center, each of these management roles focused on serving as the Team Lead for process improvement work units. She also has public administration experience secured during past assignments at the United States Department of Agriculture and the Health Resources and Services Administration.

She earned her undergraduate degree from Hampton University and a Master of Science degree from Georgetown University. She is alumni of a W.K. Kellogg Fellowship at The University of North Carolina at Chapel Hill's Kenan-Flagler Business School, earned a master's certificate in Project Management from The George Washington University, completed American University's Key Executive Leadership Program, and has Six Sigma Green Belt certification. She has a proven record in health communication, regulatory science, public health, and healthcare policy and management.

**Chrissy Cochran, PhD**
Director, FDA Office of Bioresearch Monitoring Operations

Chrissy J. Cochran, PhD is Director of the Office of Bioresearch Monitoring Operations at the FDA and is responsible for working with each of FDA's product centers to manage the BIMO program. Her staff conduct inspections of clinical and nonclinical facilities to ensure trial participants are protected and the data used to support FDA decisions are reliable. Dr. Cochran holds a PhD in Toxicology and a Bachelor of Science in Biochemistry.

**Robert Ball, MD, MPH, ScM**
Deputy Director
FDA Office of Surveillance and Epidemiology

Robert Ball, MD, MPH, ScM is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research, Food and Drug Administration (FDA) where he shares in responsibilities leading OSE staff in premarket and postmarket regulation of drugs and therapeutic biologics through adverse event surveillance, pharmacoepidemiology, risk management, and medication error prevention. From 2008-2013, he served as the Director, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, FDA where he led statistical and epidemiological evaluation of vaccines, blood, cell,

tissue, and gene therapy products. His recent research has included the application of natural language processing and machine learning to improve the evaluation of medical product safety and effectiveness in electronic healthcare data systems.

**Lauren Bateman, MS**
*Health Scientist*, FDA Office of Clinical Policy, and Programs

Lauren Bateman is a Health Scientist in the Office of Clinical Policy and Programs (OCPP) at the FDA. OCPP promotes safe, effective, and innovative medical products for patients through agency-wide collaboration on combination products, ethical conduct of clinical research, orphan product development, patient engagement, and pediatric therapeutics.

Prior to joining OCPP, Lauren was in the Office of Combination Products (OCP), which is a sub-office in OCPP and is responsible for the classification and jurisdictional assignment of combination products, as well as ensuring timely and effective premarket review and consistent and appropriate postmarket regulation for combination products.

Lauren works with the FDA medical product centers and other offices to coordinate the Agency's ongoing cross-center initiatives and fosters collaboration within FDA. Initiatives include policy development, Information Technology (IT) development and management, and process improvement. Lauren has a M.S. in Biodefense from George Mason University and a B.S. in Biological Sciences from University of Maryland, College Park. Additionally, she is a certified Project Management Professional.

**Suranjan De, MS, MBA**
*Deputy Director*
Regulatory Science Staff
FDA Office of Surveillance and Epidemiology

Mr. De is the Deputy Director of CDER's Office of Surveillance and Epidemiology, Regulatory Science Staff at FDA. He provides expert advice and technical direction on regulatory science for developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. He has over 25 years of experience with the FDA, the National Institutes of Health, and the pharmaceutical industry. His work includes compounding reporting guidance, data management of the FDA Adverse Event Reporting System (FAERS), automating triaging of voluntary reporting, E2B(R3) and Safety Reporting Portal for mandatory postmarketing electronic submissions and the FAERS Public Dashboard.

He received a Master's degree in Computer Science from the Institute for Technology and Management in India and a Master's in Business Administration from the Johns Hopkins University in Baltimore, MD.

**Laurie Muldowney, MD**
*Deputy Director*
Office of Scientific Investigations (OSI)
Office of Compliance (OC)
CDER | US FDA

Dr. Laurie Muldowney serves as the Deputy Director of the Office of Scientific Investigations (OSI) in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. In this role, she works collaboratively with the Office Director to manage the development and implementation of patient focused, risk-based inspection, compliance, and enforcement activities under the Agency Bioresearch Monitoring Program.

Dr. Muldowney joined the FDA/CDER in 2009 as a medical officer and has served in multiple positions across CDER, including clinical team leader with the Division of Gastroenterology and Inborn Errors Products in the Office of New Drugs and associate director for medical policy in the Office of Translational Science. Dr. Muldowney received a B.S. in chemistry from the College of William and Mary and earned her medical doctorate from Jefferson Medical College in Philadelphia, PA. Following additional postgraduate training, Dr. Muldowney served as a primary care physician with the United States Navy and worked in medical communications.