SPEAKER BIOGRAPHIES

Gopa Biswas, PhD
Lead Pharmacologist
Office of Study Integrity and Surveillance (OSIS)
Office of Translational Sciences (OTS)
CDER |US FDA

Gopa Biswas is a Lead Pharmacologist in the Division of New Drug Study Integrity (DNDSI), OSIS, in the Office of Translational Sciences in FDA's Center for Drug Evaluation and Research. Her work involves inspections of firms conducting regulated bioavailability/bioequivalence (BA/BE) and GLP studies in support of pre-market drug approval applications submitted to FDA.

She has conducted several domestic and foreign on-site inspections of contact research organization conducting BA/BE studies under OSIS' Bioresearch Monitoring Program (BIMO) programs. Gopa has experience in regulatory review and reliability evaluation of data submitted in support of BA/BE and GLP studies submitted to FDA in support of INDs, NDAs, BLAs and ANDAs and provide support to the CDER review divisions.

ShaAvhrée Buckman-Garner MD, PhD, FAAP
Director
Office of Translational Sciences (OTS)
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ShaAvhrée Buckman-Garner, M.D., Ph.D., FAAP is the Director of CDER's Office of Translational Sciences (OTS). OTS is comprised of the Office of Biostatistics, Office of Clinical Pharmacology, Office of Computational Science, Office of Study Integrity and Surveillance, provides oversight to CDER research involving human subjects, the CDER ORISE Program, as well as CDER regulatory science research. OTS is responsible for providing coordination for Critical Path initiatives across CDER in partnership with individual CDER offices.

Before joining OTS, Dr. Buckman-Garner served as Deputy Director for OTS and as medical team leader in CDER's Division of Pediatric Drug Development, Office of Counter Terrorism and Pediatric Drug Development. Dr. Buckman-Garner received her MD and PhD degrees with an emphasis on molecular cell biology from Washington University School of Medicine. She completed pediatric specialty training at Baylor College of Medicine.

Xikui Chen, PhD
Pharmacologist
Division of Generic Drug Study Integrity
Office of Study Integrity and Surveillance
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Xikui Chen is a pharmacologist in the Division of Generic Drug Study Integrity, Office of Study Integrity and Surveillance in the FDA's Center for Drug Evaluation and Research. He received a Ph.D. in Pharmaceutical Sciences from the University of Oklahoma in 1996. Xikui has conducted analytical inspections as well as participated in clinical inspections, and evaluated inspectional observations since joined in the Division of Scientific Investigation in 2007.

Zhou Chen, M.D., PhD
Team Lead
Office of Study Integrity and Surveillance
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Dr. Zhou Chen is the team lead for the GLP team in the Division of New Drug Study Integrity in the Office of Study Integrity and Surveillance. He received his PhD degree in Medical Sciences from Texas A&M University in 1994. He joined FDA/CDER in 1998 and has experience working as a pharmacology/toxicology reviewer in CDER OND and performing GLP and Animal Rule study inspections in CDER OSIS.

Monica Javidnia, PhD
Staff Fellow
Division of Generic Drug Study Integrity
Office of Study Integrity and Surveillance
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Monica Javidnia is a Staff Fellow in the Office of Study Integrity and Surveillance, Division of Generic Drug Study Integrity in the FDA's Center for Drug Evaluation and Research. She earned her Ph.D. in Pharmacology from Georgetown University and has experience in the conduct and review of clinical and analytical studies. Monica also has a special interest in drugs and biologics for neurodegenerative diseases.

Sean Kassim, PhD
Director
Office of Study Integrity and Surveillance (OSIS)
Office of Translational Sciences (OTS)
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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.

Lynda Lanning, D.V.M., DABT
Division of New Drug Study Integrity (DNDSI)
Office of Study Integrity and Surveillance
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Lynda Lanning, D.V.M, DABT is a member of the GLP Team in the Office of Study Integrity and Surveillance, CDER. She received her D.V.M. from Auburn University, completed a pathology residency at Argonne National Laboratory/University of Chicago and is a Diplomate of the American Board of Toxicology. At the FDA, Dr. Lanning conducts and evaluates inspections of nonclinical studies submitted in support of pharmaceutical development. She is a member of the Whole-slide imaging working group (WG), Data Integrity/Quality Systems for BA/BE studies WG, BIMO Compliance Program subcommittee, FDA Animal Welfare Council Subcommittee, GLP Update WG, CDISC/STP/FDA WG for Tumor Combinations and the ESTP International Clinical Pathology WG. Prior to joining FDA, she served as the toxicologist/toxicologic pathologist in the Office of Regulatory Affairs, DMID, NIAID, NIH for 11 years. Her expertise in toxicologic pathology, regulatory toxicology, safety assessment, drug development and regulatory strategy was used extensively at NIAID to assist in the development of small molecules and biologics to treat or prevent diseases including TB, zika, filoviruses, EEE/WEE, anthrax, malaria, schistosomiasis, plague, tularemia, Burkholderia, Hendra, Nipah and influenza. She was responsible for making complex regulatory and development recommendations based on results of nonclinical studies and served as lead auditor and monitor for DMID-supported GLP-compliant and non-GLP studies intended for submission to the FDA including those supporting Animal Model Qualification and studies submitted under the Animal Rule. She was regulatory manager and toxicologist/pathologist for 4 AMQ packages (plague, tularemia and anthrax- cynomolgus macaque, NZW), 6 PINDs and 3 Master Files and played a key role in leading the NIAID Team through the successful Advisory Committee meeting and subsequent approval of ciprofloxacin label change adding the treatment of pneumonic plague.

Prior to NIAID, her professional experience included work with National Toxicology Program (peer review pathologist), in vivarium management, medical device product development, regulatory nonclinical pharmaceutical safety assessment (small molecule and biologics), and development of unique compounds for biodefense, zoonotic and orphan diseases. She has authored numerous peer-reviewed publications and is an active member of national and international professional societies related to laboratory animal science, toxicology and toxicologic pathology.

Amanda Lewin, PhD
Division of Generic Drug Study Integrity (DGDSI)
Office of Study Integrity and Surveillance
Office of Translational Sciences (OTS)
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Amanda Lewin is a team lead in the Division of Generic Drug Study Integrity (DGDSI). She was previously a reviewer in the Division of New Drug Study Integrity (DNDSI) and planned, conducted, and directed regulatory inspections in support of ANDAs, NDAs, and BLAs. Before joining OSIS in 2016, Amanda completed her Ph.D. in Pharmacology at Georgetown University, her MFS in Forensic Toxicology from The George Washington University, and BS in Chemistry from the University of California, Santa Barbara.

Xingfang Li, M.D., RAC
Pharmacologist
Division of Generic Drug Scientific Integrity
Office of Study Integrity and Surveillance
Office of Translational Sciences (OTS)
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Dr. Xingfang Li is a Pharmacologist in the Division of Generic Drug Scientific Integrity, within the Office of Study Integrity and Surveillance/Office of Translational Sciences/Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Dr. Li started at the FDA in 2010 as an FDA Commissioner's Fellow in the Office of Chief Scientific Officer, and then joined the Office of Study Integrity and Surveillance in 2012. In OSIS, Dr. Li has coordinated, conducted, and reviewed FDA BIMO clinical and analytical inspections in support of NDAs, ANDAs, BLAs, Biosimilars, and INDs. She was a member of the Revision Working Group for the clinical portion of CP 7348.003. Prior to her FDA career, she had 13 years of experience in the US pharmaceutical industry. Dr. Li has education and training in medicine, biomedical informatics, and neuroscience.

Sripal Reddy Mada, PhD
Pharmacologist
Division of Generic Drug Study Integrity
Office of Study Integrity and Surveillance
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Sripal Reddy Mada joined the FDA in 2008 as clinical pharmacologist in the Office of Clinical Pharmacology (OCP). Later moved to Office of Scientific Investigations (OSI), Office of Compliance (OC), and is currently a senior pharmacologist in Office of Study Integrity and Surveillance (OSIS), Office of Translational Sciences (OTS).
Received bachelor's in pharmacy and Ph.D. in pharmaceutical sciences from the Kakatiya University, India. Completed post-doctoral research in Sol Sherry Thrombosis Research Center, Temple University School of Medicine, Philadelphia, PA. Before joining FDA, was a research assistant professor in University of Pittsburgh School of Pharmacy, Pittsburgh, PA. Regulatory experience includes evaluation of bioanalysis for bioavailability / bioequivalence, pharmacokinetic, and clinical pharmacology studies submitted under INDs, NDAs BLAs and ANDAs. Have good experience in on-site inspections and remote record reviews of clinical and bioanalytical facilities across the globe, actively involved in regulatory policy, guidance development, conferences and workshops related to bioanalysis.

Gajendiran Mahadevan, PhD
Pharmacologist
Office of Study Integrity and Surveillance
Office of Translational Sciences (OTS)
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Gajendiran Mahadevan, Ph.D., Pharmacologist joined the Agency as an FDA Commissioner Fellow in the Center for Veterinary Medicine and later moved to Center for Drug Evaluations and Research in the Office of Study Integrity and Surveillance. He has been involved in the Bioresearch Monitoring program for conducting inspections and alternative inspections.

Tahseen Mirza, PhD
Associate Office Director for Regulatory Affairs
US Food and Drug Administration

Dr. Tahseen Mirza is an accomplished scientist and leader with over twenty years of industrial and regulatory experience in the areas of generic and branded pharmaceutical development. He holds a Ph.D. in Pharmaceutical Sciences from University of Cincinnati. In his current job, Dr. Mirza is Division Director of the FDA Office of Manufacturing and Product Quality's (OMPQ) Division of Policy, Collaboration and Data Operations (DPCDO). Prior to joining OMPQ, Dr. Mirza was the Deputy Director of the Division of Product Quality Research (DPQR), within The Office of Pharmaceutical Science's (OPS) Office of Testing and Research (OTR). Before joining the FDA, he was a Director in the Technical R&D department of Novartis Pharmaceutical Corp, East Hanover, NJ. During his career, Tahseen has led groups of chemists and Ph.D. level scientists in various R&D and QC/QA departments and is well versed in both early and late phase product development. He has enabled the transfer of manufacturing processes and analytical methods globally between R & D and manufacturing and contract manufacturers. He has also worked in various capacities for Sanofi Aventis, Merial/Merck and the United States Pharmacopeia. At the USP he served as a USP Liaison between FDA, industry and three USP Expert Committees; Dissolution and Bioavailability (Biopharmaceutics), Pharmaceutical Dosage Forms and Biostatistics he coordinated the efforts towards establishing sound analytical methods and compendial monograph standards. He has lectured and trained industry and FDA scientists in Manufacturing Science, Biopharmaceutics and Dissolution. He has moderated national and international conferences and workshops on variety of topics such as drug release, dissolution, QbD and PAT. Dr. Mirza has lectured and trained industry and FDA scientists in Manufacturing Science, Biopharmaceutics and Dissolution. He has co-authored more than 30 research articles. He has moderated national and international conferences and workshops on variety of topics such as drug release, dissolution, QbD and PAT. Dr. Mirza is the founding Chairman of the AAPS focus group, In Vitro Release and Dissolution.

Doug B. Pham, Pharm.D., J.D.
Associate Director of Clinical Policy
Office of Study Integrity and Surveillance
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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.

Sarmistha Sanyal, PhD
Chemist
Division of Generic Drugs Study Integrity | Office of Study Integrity and Surveillance
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Sarmistha Sanyal is a Chemist in the Office of Study Integrity and Surveillance within FDA's Center for Drug Evaluation and Research. She received a Ph.D. in biochemistry from University of Minnesota 2010. Sarmistha has experience in conducting inspections/remote record reviews for bioequivalent and bioavailability studies. She has extensive experience to use knowledge management technique to support CDER's regulatory information infrastructure. As a team member of CDER's Biomarker Qualification Program, she had contributed towards Guidance and policy development of biomarkers as a Drug Development Tool (DDT).

Kara Scheibner, PhD
Pharmacologist
Division of Generic Drug Study Integrity (DGDSI)
Office of Study Integrity and Surveillance Session (OSIS)
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Kara A. Scheibner, PhD is a Pharmacologist in the Division of Generic Drug Bioequivalence Evaluation within the Office of Study Integrity and Surveillance/Office of Translational Sciences/Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Dr. Scheibner earned a B.S. in Pharmacology/Toxicology from the University of Sciences in Philadelphia, Pennsylvania and a PhD in Pharmacology and Molecular Sciences from The Johns Hopkins University School of Medicine in Baltimore, Maryland under the mentorship of Philip A. Cole, M.D, Ph.D. Following postdoctoral training in cell biology/immunology and molecular biology/cancer, she was appointed Assistant Professor at the University of Maryland, School of Medicine in the Center for Stem Cell Biology and Regenerative Medicine where she continued her work in cancer research, specifically assessing the role of microRNAs on hematopoietic and leukemia stem cells. While there, she also taught and co-directed several courses in the graduate school, was a member of the Molecular Medicine admissions committee and multiple thesis committees and mentored/trained students at the graduate and undergraduate levels. Dr. Scheibner joined the FDA as a Pharmacologist in July of 2014.

Paul Li-Hong Yeh, PhD
Division of New Drug Study Integrity (DNDSI)
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Paul Yeh had joined FDA since 2014. He graduated from University of Missouri and had post graduate training at the Johns Hopkins University. He is interested in bioengineering, bioanalytical analysis and biologics products review, inspection, and regulation.

Cynthia (Yiyue) Zhang PhD, RAC
Senior Staff Fellow
Division of New Drug Study Integrity (DNDSI)
Office of Study Integrity and Surveillance Session (OSIS)
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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.