

Instructor Biographies



Terrell Baptiste, MBA

Senior Manager, Regulatory
Policy and Intelligence

Gilead Sciences, Inc.

Terrell Baptiste has over 15 years of experience in medical product development spanning legislative policy, roles in government, asset management, and commercial and regulatory roles in biotech. He currently serves as Senior Manager, Regulatory Policy and Intelligence Gilead Sciences.

At Gilead, Terrell supports the Regulatory Affairs and Development organization and works on regulatory strategies to leverage innovative regulatory programs for oncology programs at Gilead. He also has a successful track record of successfully forging asset management collaborations and providing perspective on regulatory topics related to drug development. Terrell has also had an active role on commercial teams where he planned necessary steps for market preparation and patient access. Terrell has served at the U.S. Food and Drug Administration, in CDER's stakeholder engagement office and previously was the founding member of the regulatory policy team at BioMarin.



Akintunde (Tunde) Bello, PhD

Vice President of Clinical
Pharmacology and
Pharmacometrics

Bristol-Myers Squibb

Akintunde (Tunde) Bello is Vice President of Clinical Pharmacology and Pharmacometrics at Bristol-Myers Squibb and leads a cross-functional team of scientists working on early and late stage clinical development of novel immuno and targeted oncology therapies. Tunde also oversees the quantitative systems pharmacology, physiologically based pharmacokinetics and model based meta-analysis functions. Prior to his role at BMS, Tunde was a Clinical Pharmacology Group Leader at Pfizer Inc where he oversaw the life cycle management support of the oncology and pain and inflammation therapeutic areas. Tunde's more than 25 years of pharmaceutical industry experience encompasses the areas of bioanalysis, preclinical DMPK and clinical drug development. He have supported the development, approval and life cycle management of more than 6 marketed drugs in the areas of oncology, pain management, inflammation and infectious disease. Tunde has a BSc in Medical Laboratory Sciences (Biomedical Sciences) from Portsmouth University (UK), an MSc in Instrumentation and Analytical Sciences from the University Of Manchester Institute Of Science and Technology (UMIST, UK) and a PhD in Pharmaceutical Sciences from King's College, University of London (UK). Tunde has authored/co-authored more than 70 peer reviewed abstracts and journal manuscripts and is a member of the American Society of Clinical Pharmacology and Therapeutics (ASCPT, served on the annual meeting organizing committee) and the American Society of Clinical Oncology (ASCO). He is the recent post Chair of the IQ Consortium Clinical Pharmacology Leadership Group.

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Nageshwar Budha, PhD

Senior Director, Clinical
Pharmacology

BeiGene

Nageshwar Budha has 12 years of industry experience in the areas of clinical pharmacology and pharmacometrics. He is currently working as Senior Director, Clinical Pharmacology at BeiGene and serves on the editorial board at the Clinical and Translational Science Journal. Before his current role, Dr. Budha worked in the clinical pharmacology group at Genentech with increasing roles of responsibility. Over the course of his career Dr. Budha worked on small molecule and large molecule drug development projects in oncology and non-oncology therapeutic areas and supported regulatory approvals. Dr. Budha received multiple recognition awards for his work and at the school. Dr. Budha received his PhD from the University of Tennessee Health Science Center at Memphis and his BS and MS degrees in Pharmaceutical Sciences from Kakatiya University, India.



James Crawford, PhD

Senior Principal Scientist

Genentech

Dr. James Crawford is a Senior Principal Scientist and Project Team Leader in Small Molecule Drug Discovery at Genentech. Born and raised in Glasgow, Scotland, James obtained his MSci and Ph.D. degrees in chemistry from the University of Strathclyde, in addition to building an affinity for watching Rangers F.C. and listening to The Smiths. He joined Professor K.C. Nicolaou's laboratory at The Scripps Research Institute as a Fulbright scholar, then started his industrial career in 2006 with AstraZeneca in their Respiratory and Inflammation group. In 2010, he moved to Genentech, where he has worked across Immunology, Oncology, Antibacterials, and Regenerative Medicine. One of his key roles has been as the chemistry leader of the BTK project team at Genentech, resulting in the discovery of Fenebrutinib which is in Ph3 clinical trials.

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**Justine Cunningham,
PhD, DABT**

VP, Toxicology &
Biodistribution

Sana Biotechnology, Inc.

Justine graduated from The University of Queensland, Brisbane, Australia in 1998 with a PhD in Neuroscience. Thereafter she moved to Memphis to pursue her Post-doc at St Jude Children's Research Hospital on a cross functional project between the Dept's of Developmental Neurobiology and Tumor Cell Biology. Later she took a chance on a new gene therapy company in late 2001 pursuing genetic therapies to express neurotrophic factors for Parkinson's and Alzheimer's. Following that she has worked at a variety of small and mid-size pharma continuing in the space of advancing novel biologics, leading to the successful filing of multiple INDs and entry into patients. Today Justine leads Toxicology, Pathology, and Biodistribution at SANA Biotechnology. SANA is an emerging player in leveraging genetic technologies to deliver novel cell and gene therapeutic medicines to meaningfully improve patient outcomes and to make these broadly accessible to the people who need them.



Dolo Diaz, PhD

Head of Development
Sciences

Denali Therapeutics

Dolo Diaz serves as the Head of Development Sciences at Denali Therapeutics. In this role she leads the DMPK, Clinical Pharmacology, Toxicology, Pathology and Nonclinical Operations teams in the advancement of Denali's portfolio of small molecules and biotherapeutics. Dolo was previously the Senior Director of Safety Assessment at Denali Therapeutics. In this role she built and led a group with expertise in toxicology, pathology and nonclinical operations. Prior to that Dolo was the Head of Discovery Toxicology at Genentech, where for nine years she led compound optimization and safety strategies for the small molecule discovery portfolio across therapeutic areas. Dolo started her industry career at Eurofins, where she established and headed the In-vitro Toxicology group. Dolo received her PhD in Toxicology from the University of Washington, followed by post-doctoral work at the Fred Hutchinson Cancer Research Center in Seattle. She has a BS in Pharmacy from the University of Santiago de Compostela (Spain). Dolo has authored more than 30 peer-reviewed publications and she is a Diplomate of the American Board of Toxicology.

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Gayle Derfus, PhD

Executive Director,
Drug Substance Process
Development

Gilead Sciences

Gayle Derfus has 15 years of experience in process development spanning all phases of product development. She currently serves as Executive Director, Drug Substance Process Development at Gilead Sciences. In this role Dr. Derfus is responsible for end-to-end process development and manufacturing support for biologics drug substance, including cell line development, cell culture process development, purification process development, and pilot plant operations. Her team supports manufacturing at both internal Gilead manufacturing sites and external partner sites. Dr. Derfus has also led several cross-functional product development teams. Prior to joining Gilead in 2011, Dr. Derfus worked at Genentech in upstream process development. Dr. Derfus received her PhD in Bioengineering from the University of California at San Diego and her BS degree in Engineering Science and a minor in Spanish from Iowa State University.



Mika Derynck, MD

Chief Medical Officer

Amunix Pharmaceuticals

Mika Derynck has over 25 years of clinical academic, and drug development experience. She is currently the Chief Medical Officer at Amunix Pharmaceuticals working on pro-drug T-cell engagers and cytokines for oncology. Prior to Amunix, Mika was at Genentech/Roche for 15 years where she led the Franchises for Cancer Immunotherapy, Gastrointestinal/Genitourinary, and the China Development Team for Product Development Oncology. Before that she led the Breast Cancer Franchise. Prior to that she was in Early Development, gRED, where she had oversight on the PI3K, AKT, mTOR, MEK programs from preclinical to phase I and II. She has extensive regulatory experience from IND for first-in-human studies, phase II-III, global full and accelerated approvals, negotiation of post marketing requirements and conversions of accelerated approval, and registration of non-registrational studies (phase 2 or cooperative group study). Drugs include Avastin, Tecentriq, Perjeta, Cotellic, Taselisib, Pictilisib, Ipatasertib, Apatolisib, GDC-0810, GDC-0623, GDC-0349, anti-IGF1R. Mika is trained in Internal Medicine and Medical Oncology, having received her M.D. at Boston University, residency at Johns Hopkins University, and fellowship at University of California, San Francisco. Shortly after completion of her fellowship, she joined the faculty at UCSF and continued her clinical and translational research work in Prostate Cancer.

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Mark Dresser, PhD

Senior Vice President,
Biomarker Sciences &
Clinical Pharmacology

Gilead Sciences

Mark Dresser has over 20 years of experience in medical product development spanning all phases of R&D in start-up, biotech, pharma, and academic environments. He currently serves as Senior Vice President, Biomarker Sciences and Clinical Pharmacology, and the Global Development Leader of the 2nd Generation Remdesivir program at Gilead Sciences. Dr. Dresser is also an Adjunct Full Professor in the Department of Bioengineering and Therapeutic Sciences at UCSF, and serves as the President-Elect of the American Society for Clinical Pharmacology & Therapeutics (ASCPT). Dr. Dresser's prior appointments include Senior Vice President, Development Sciences at Denali Therapeutics and Head of Oncology Clinical Pharmacology and Project Team Leader for the Anti-PD-L1 [Tecentriq®] program at Genentech. He began his career at ALZA Corporation, a Johnson & Johnson company. Over the course of his career, Dr. Dresser has played a key role in the advancement of over 50 investigational drugs into clinical testing and the global regulatory approval of four novel oncology therapies. In 2019, Dr. Dresser received the UCSF Graduate Division Alumnus of the Year Award for his contributions to science and medicine. Dr. Dresser received his PhD from the University of California at San Francisco and his BS and MS degrees in Chemistry from Rensselaer Polytechnic Institute and the Swiss Federal Institute of Technology.



JW Feng, PhD

Staff Research Scientist

Google Research

JW is a Staff Research Scientist and leads the drug discovery team in [Google Accelerated Science](#). He is applying Google technologies, including deep learning, to accelerate the discovery of small molecule drugs. JW was an early employee in a biotech startup, Denali Therapeutics, where he built the molecular modeling and data science group to support both small molecule and biotherapeutics discovery. Key contributions from JW lead to the invention of multiple molecules entering clinical trials. Prior to Denali, JW was a Scientist at Genentech supporting small molecule drug discovery. JW received a PhD in Computational Biology at Washington University in St. Louis and bachelor of science degrees in Computer Science and Biochemistry at The Ohio State University.

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Richard Graham, PhD

Senior Vice President,
Development

Theravance Biopharma

Richard A. Graham is Senior Vice President, Development, at Theravance Biopharma where he is responsible for leading the progression of late-stage clinical assets through regulatory filing and approval. Since joining Theravance Biopharma, Dr. Graham has served as Vice President of Clinical Pharmacology, and more recently, as Vice President of Clinical Development. Prior to joining Theravance Biopharma, Dr. Graham spent five years at GlaxoSmithKline working in the area of Drug Metabolism and Pharmacokinetics, seven years at Genentech/Roche as a clinical pharmacologist and Global Development Team Leader, and one year at Onyx Pharmaceuticals where he headed Translational Medicine. In his nearly 20-year career, he has worked across all stages of drug development and all major therapeutic areas. Dr. Graham received his Bachelor's and Master's degree in Biochemistry from Iowa State University and his Doctorate of Philosophy degree in Pharmaceutical Sciences from The University of North Carolina at Chapel Hill.



Conny Irl, PhD

Vice President
Global Head Data &
Statistical Sciences –
Oncology

Genentech

Conny Irl has been working in the biotech/pharmaceutical industry for more than 20 years, across all phases of R&D and multiple therapeutic areas. She is currently Vice President and Global Head Data & Statistical Sciences (DSS) Oncology at Genentech, providing oversight from a DSS perspective for the late stage solid tumors portfolio. Dr. Irl started her career in the Biostatistics Department of Hoffmann-La Roche in Nutley, NJ, which she joined in 1999. In 2004, she transferred to the Roche Headquarters in Basel and in 2011 to Genentech in South San Francisco, which provided her unique opportunities to experience and bridge different cultures and work styles. During her time at Roche and Genentech, Dr. Irl has played a key role in the clinical development and regulatory approval of a number of oncology drugs, such as Alectinib™, Avastin™, Cotellic™ and Tecentriq™. Dr. Irl has also held a number of cross-functional leadership roles, such as Global Development Team Leader for Avastin Gynecological Cancers. Dr. Irl received her Ph.D. in Statistics from the Ludwig-Maximilians-University in Munich, Germany.

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Lawrence Lin, PhD

Director, External Relations
and Outreach

UCSF-Stanford CERSI

Lawrence Lin is Director of External Relations and Outreach at the UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (UCSF-Stanford CERSI). In this role, he manages and oversees all CERSI activities especially in education and outreach, and serves as the liaison between the UCSF-Stanford CERSI and FDA or external entities. Prior to joining CERSI, Lawrence was an ORISE fellow in the FDA's Center for Drug Evaluation and Research, Office of Clinical Pharmacology. He has over ten years of experience in scientific program management involving cross-sector collaborations, having previously served as the Project Director of the NIH-funded Pharmacogenomics Research Network, as well as the International Transporter Consortium. Lawrence received his PhD in Pharmaceutical Sciences and Pharmacogenomics from the University of California San Francisco, and a BS in Biological Sciences with additional majors in anthropology and history from Carnegie Mellon University.



Patrick Loerch, PhD

Senior Vice President,
Data Sciences & Biometrics

Gilead Sciences

Patrick Loerch has over 20 years of experience in data sciences, real world evidence and genomics research spanning all phases of R&D within the pharmaceutical industry. Dr Loerch currently serves as Senior Vice President, Data Sciences and Biometrics at Gilead Sciences. In addition to oversight of the existing Biometrics and Epidemiology organizations, Dr. Loerch is accountable for the build out and integration of Real World Evidence and Data Sciences capabilities to accelerate the discovery, development and delivery of new medicines. Dr. Loerch's prior roles include leadership positions at Johnson & Johnson, Celgene and Merck. He began his career at Rosetta Inpharmatics, a genomics start-up in Seattle, WA that was later acquired by Merck. Dr. Loerch received his PhD in Biostatistics from the Harvard University and his BS in Biochemistry from Washington State University.

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Raj Madabushi, PhD

Associate Director, Guidance
and Scientific Policy, Office of
Clinical Pharmacology,
OTS/CDER

U.S. Food and Drug
Administration

Rajanikanth (Raj) Madabushi has over 15 years of regulatory experience. As a Pharmacometrics Reviewer and Clinical Pharmacology Team Lead, Dr. Madabushi has played a key role in the advancement and application of quantitative clinical pharmacology approaches for regulatory decision making and addressing various drug development issues. He currently serves as the Associate Director, Guidance and Scientific Policy in the Immediate Office of Office of Clinical Pharmacology. Dr. Madabushi is also the CDER Point-of-Contact for the PDUFA VI MIDD Paired Meeting Pilot Program and the Rapporteur for ICH M12 Expert Working Group – Drug Interaction Studies. Dr. Madabushi received his PhD in Pharmaceutical Sciences from Birla Institute of Technology and Sciences (BITS), Pilani, India.



**Heidi Marchand,
PharmD, RPh**

Executive Director and Head
of Global Regulatory Policy &
Intelligence

Gilead Sciences

Heidi Marchand, PharmD, RPh is Executive Director and Head of Global Regulatory Policy & Intelligence and leads Gilead's efforts to develop and implement strategies to shape and influence regulatory policy in selected areas of interest in the external regulatory environment in line with Gilead's mission to advance innovative therapeutics and improve patient care. Heidi joins Gilead from the U.S. FDA where she served for the last 11 years as Assistant Commissioner, Office of Health Affairs in the Office of the Commissioner. She represented U.S. FDA on high-profile and complex matters of new policies and programs that impact patients and other stakeholders. Achievements during her tenure at U.S. FDA include supervision of an office of over 20 multi-disciplinary science and health professionals to evaluate stakeholders' activities and respond to public health emerging and urgent issues across therapeutic areas. Prior to joining the U.S. FDA, Heidi was Head of Global Regulatory Policy and Intelligence at both Amgen and Pfizer. In addition, she worked within Regulatory Affairs at Novartis and also served for 6 years at FDA where she was Executive Secretary for the National Task Force on AIDS Drug Development, chartered by the Secretary of Health and Human Services to advise on AIDS drug development barriers. Heidi holds a Doctor of Pharmacy from the Medical College of Virginia.

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Andrew McKee, MD

Founder, CEO, and President
Headland Strategy Group

Andrew has over 15 years' experience in biotechnology, pharmaceuticals, diagnostics, and other healthcare sectors. He founded Headland Strategy Group to build a team of smart, service-oriented problem-solvers who are passionate about health care innovation. He loves to build relationships, lead teams, teach, mentor, brainstorm, and work on difficult projects. Headland Strategy Group provides management consulting services for biopharma, diagnostics, digital health, and medical device firms. Headland's value proposition is that they offer: 1) a hybrid strategy model (Commercial Strategy, BD/M&A/Partnering, and R&D/Portfolio Strategy); 2) deep expertise across diseases and technologies; 3) a flexible, results-oriented service that pairs well with fast-moving client teams; and 4) strong exposure to the US and Japan/S. Korea with offices and clients in the US and Japan. Headland is proud to serve distinctive clients such as Denali, NGM Bio, Alector, Gilead, Roche/Genentech, Theravance, Ultragenyx, Gyroscope, Olema, EA Pharma, SNBL, Alfresa Group, and many others. Andrew's background includes having worked for McKinsey and Company, Google, and Genentech. He holds B.S.E. and M.D. degrees from Duke University. He is a husband, father, mindfulness meditator, professional saxophonist, published writer, former scientist, and licensed patent holder.



Aine Miller, PhD

Vice President, Regulatory
and Medical Writing
Theravance Biopharma

Dr Áine Miller joined Theravance Biopharma in Feb 2019 as the Vice President of Regulatory and has since expanded her role to also overseeing medical writing. Prior to joining Theravance Biopharma, Dr. Miller spent five years at Alkermes where she was the Global Senior Director of Regulatory and held responsibility for regulatory strategy across multiple development programs. In this role she also served as the Development Team Leader for a late-stage program through to NDA approval. Prior to Alkermes, Dr Miller led global regulatory strategic activities for commercial and development programs at Elan. Before that she worked at Allergan Medical, where she held various regulatory roles of increasing responsibility. Over her career, Dr Miller has worked on all stages of drug development providing global regulatory strategic leadership and has led negotiation with EMA, FDA and International Regulatory Agencies across a range of therapeutic areas. Dr. Miller holds a BSc and PhD in Biotechnology from Dublin City University.

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Rhea Nersesian

Senior Companion Dx Project
Leader

Genentech

Rhea Nersesian has been with the Roche organization for over 30 years, holding various positions in a wide breath of areas in the Diagnostics Division including R&D, Patent Law, and Regulatory Affairs. She is currently part of the Companion and Clinical Diagnostics Team at Genentech in SSF, California, where she supports diagnostic developments in both oncology and non-oncology programs.

Rhea has a B.S. in Genetics from UC Berkeley and an M.S. in Biotechnology and Innovation Regulatory Science from Purdue University. She began her career at Cetus Corp in Emeryville, CA, contributing to the early development of PCR.



**Roshy Pakdaman,
PhD**

Vice President,
Formulation & Process
Development

Gilead Sciences

Roshy Pakdaman has over 24 years of experience in academia and biotech environments. She is currently heading the Formulation and Process Development at Gilead Sciences and is responsible for lead optimization of pre-clinical drug candidates, preformulation, formulation development, process scale-up, technology transfer, and validation of clinical drug candidates.

Dr Pakdaman's prior appointments include, visiting scholar at California Institute of Technology and associate professor at the University of Paris Denis Diderot (France). Over the course of her career, Dr. Pakdaman has filed more than 14 patents and played a key role in the advancement of over 200 investigational drugs into clinical testing and the global regulatory approval of Veklury®, Sovaldi®, Harvoni®, and Vosevi®. Dr. Pakdaman received her PhD in physical chemistry from the University of Paris Denis Diderot (France). She was the recipient of ACS Heroes of Chemistry Award and YWCA Silicon Valley Tribute to Women Award in 2015 and 2019, respectively.

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**Heleen Scheerens,
PhD**

Senior Director, Global Head
OMNI-Biomarker
Development

Genentech

Heleen has worked in the area of pharmacology for over 20 years and her interests are in understanding the mechanisms of action of novel therapeutics in human diseases, and using translational pharmacology to improve the effectiveness of clinical development. Currently, Heleen is the Global Head of Genentech's OMNI-Biomarker Development department and leads a diverse group of >60 science professionals. Biomarker strategies from her group impact key drug development decisions in all phases of clinical development in **Ophthalmology**, **Metabolism**, **Neuroscience**, **Immunology** and **Infectious diseases**. Heleen has a passion for mentoring and is actively involved in gWise: Genentech Women in Science and Engineering, an organization committed to developing women leaders.

Prior to joining Genentech in 2006, Heleen held leadership positions at Celera Genomics and Rigel Pharmaceuticals. Heleen received her PhD in Immunopharmacology from the University of Utrecht, The Netherlands.



Kimberly Wilson, MS

Executive Director,
Translational Epidemiology

Bristol-Myers Squibb

Kimberly Wilson is an epidemiologist with over 20 years of health care research experience. Currently she is Executive Director, Translational Epidemiology at Bristol Myers Squibb. Her previous roles in industry have included pharmacovigilance and scientific stewardship in support of early and late stage drug development. Prior to joining industry, she worked in academia and the Translational Research Trials Office at the Cincinnati Children's Hospital where she managed investigator-initiated IND studies being conducted in children and adults with rare diseases. In this role, her work led to the first non-surgical therapy approved by the FDA for treatment of brain tumors occurring in Tuberous Sclerosis patients. Her work has led to multiple publications including publications in journals such as Chest and the New England Journal of Medicine.

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**Issam Zineh, PharmD,
MPH**

Director, Office of Clinical
Pharmacology, CDER

U.S. Food and Drug
Administration

Issam Zineh is Director of the Office of Clinical Pharmacology (OCP) at the U.S Food and Drug Administration (FDA) and President of the American Society for Clinical Pharmacology and Therapeutics (ASCPT). He has held various leadership positions at FDA including Associate Director for Genomics in OCP (2008-2012) and Co-Director of the CDER Biomarker Qualification Program (2009-2015), and serves on the CDER Medical Policy Council, Drug Development Tool Committee, and Drug Labeling Coordinating Committee. Dr. Zineh received his PharmD from Northeastern University and completed his residency at Duke University Medical Center. He completed a fellowship in cardiovascular pharmacogenomics at the University of Florida (UF) where he also obtained his MPH in Health Policy and Management. Dr. Zineh is a recognized expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of over 260 regulatory, research, program/project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.