In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods
Best Practices and Scientific Considerations for ANDA Submissions

Virtual Public Workshop
August 18th, 19th, and 20th
2021

Speaker Biographies

Josephine E. Aimiuwu, Ph.D.
Pharmacologist
Division of Bioequivalence II, Office of Bioequivalence
Office of Generic Drugs | CDER | U.S. FDA

Dr. Josephine Aimiuwu is a Pharmacologist/Assessor in the Division of Bioequivalence II/Office of Bioequivalence at OGD and is primarily involved with the assessment of the bioequivalence portion of abbreviated new drug applications and post-approval supplements. She joined FDA in 2010 and has experience evaluating bioequivalence studies conducted for various drug products such as solid orals (IR and MR), and narrow therapeutic drugs. She also has experience in complex drug products such as, topical non-corticosteroids and corticosteroids, ophthalmic and abuse deterrent formulations. Dr. Aimiuwu stepped away from FDA for 4 years to do some work in Bangladesh and Nigeria, where she gained further experience in global regulatory framework as a Senior Technical Advisor with USAID-funded NGOs. In that role, she provided technical assistance and facilitated the leveraging of resources with consortia of global partners to strengthen the countries' Generic Drug Regulatory Program. She obtained her Ph.D. in Pharmaceutics from the Ohio State University, Columbus, Ohio.

Ajay Banga, Ph.D.
Professor and Chair of Pharmaceutical Sciences
Mercer University

Dr. Ajay K. Banga is Professor and Department Chair in the College of Pharmacy, Mercer University, in Atlanta, GA. He also holds an Endowed Chair in transdermal delivery serves as co-Director for the Center for Drug Delivery Research. He has mentored 40 Ph.D. students as their major advisor, served on over 60 dissertation advisory committees, and his laboratory has been funded by over 100 grants/contracts from pharmaceutical and cosmetic companies, and by federal funds. He has written three books, published 165 manuscripts, 12 book chapters, and made over 260 conference presentations with his students. He has given over 90 invited lectures and served as a referee for over 40 journals. He is a Fellow of the American Association of Pharmaceutical Scientists. Dr. Banga has a Ph.D. in

pharmaceutical sciences from Rutgers University, NJ, and he has served as a consultant to over 25 companies.

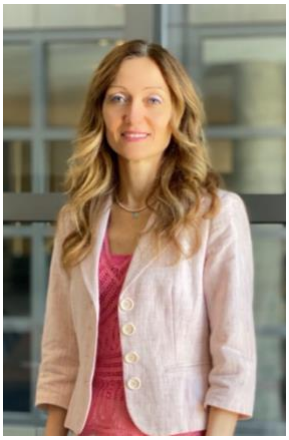
Edward Dennis Bashaw, Pharm.D.
Former Senior Science Advisor
OCP | OTS | FDA

Dr Bashaw retired from the US Food and Drug Administration in July 2021 following a career at the FDA totaling 34yrs. He joined the FDA in August 1987 in the then Division of Biopharmaceutics in the pulmonary and over-the-counter drug review area. Thirty of those years were as a member of the US Public Health Service Commissioned Corps where he rose from being a primary reviewer to the position of a Division Director in the Office of Clinical Pharmacology. Upon reaching mandatory retirement from the USPHS-CC in 2017, Dr. Bashaw returned to the FDA and became a Senior Science Advisor in the Office of Clinical Pharmacology Immediate Office. During this he led the Office of Clinical Pharmacology policy work in the area of over-the-counter drugs, sunscreen absorption and most recently the contamination issues associated with topical antiseptics. Throughout his career he has been an advocate for the application of Clinical Pharmacology to solving drug development problems and has either proposed or led such initiatives as the use of naltrexone blockade in opioid drug development, the effect of external heat on topical products, and the use partial AUC in the assessment of orally administered topical drugs (mesalamine). He is most known for his development and implementation of the Maximal Usage Trial paradigm for topically applied products which was translated into an FDA Guidance document and has been a major element in the evaluation of sunscreen absorption.

Charles Bon, M.S.
President/Founder
Biostudy Solutions, LLC

Chuck Bon is the President of Biostudy Solutions, LLC, a small company providing consulting services to the pharmaceutical industry for bioavailability/bioequivalence clinical study design and pharmacokinetic and statistical evaluations. He and his staff provide statistical evaluations for bioequivalence of in-vitro data, including for IVPT. Chuck founded Biostudy Solutions in 2005 to leverage off his nearly 40 years' experience in Phase I CROs. He served as a member of FDA's expert panel for Bioequivalence of Topical Corticosteroids and FDA's Blue Ribbon panel on Population and Individual Bioequivalence. He is co-author, with the late Sanford Bolton, of the 4th and 5th editions of "Pharmaceutical Statistics". Chuck has contributed to, or written, a number of chapters in various pharmaceutical books, is a co-author on a number of scientific papers and regularly presents at scientific meetings. Chuck is a founding trustee and board member of SAAMnow.

Pina D'Angelo, M.S.
Vice President of Biometrics
Innovaderm Research



Pina D'Angelo holds a Bachelor and a Master's degree in Mathematics & Statistics from McGill University, Canada. She has worked in the Pharmaceutical industry for over 25 years, both on the generic as well as the innovator side. In her most recent role, she acts as Vice President of Biometrics at Innovaderm Research. Pina has extensive experience in many therapeutic areas in clinical trials, ranging from Phase 1 to 4 studies, as well as in PK/PD and bioequivalence studies. Prior to joining Innovaderm, she worked for Novum PRS, PRACS Institute, Pfizer Canada, MDS Pharmaservices, Astra Pharmaceuticals and IMS Health. The main topics of her recent research include handling of missing data and outlier considerations in in-vitro permeability testing. Pina has also given Statistics courses to undergraduate and graduate students at various universities and colleges in Montreal and Toronto.

Priyanka Ghosh, Ph.D.
Senior Pharmacologist
ORS | OGD | CDER | FDA

Dr. Priyanka Ghosh is a senior pharmacologist within the Division of Therapeutic Performance. Her areas of expertise include products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh leads regulatory science research initiatives related to topical and transdermal drug products, including projects related to development of noninvasive imaging techniques for evaluation of cutaneous pharmacokinetics, under the GDUFA regulatory science program. Dr. Ghosh also leads the development of general and product-specific guidances, review strategies for pre-ANDA meeting requests and citizen petitions and is the co-chair of the Bioequivalence Standards for Topicals Committee within OGD. Prior to joining FDA, Dr. Ghosh completed her Bachelor's degree in Biotechnology from West Bengal University of Technology (India) and a Ph.D. in Pharmaceutics and Drug Design from the University of Kentucky.

Tapash Ghosh, Ph.D.
Team Lead and Master Reviewer at the Biopharmaceutics Division
ONPD | OPQ | CDER | FDA

Tapash Ghosh is the Team Lead and a Master Reviewer of the Biopharmaceutics Division at the Office of New Drug Products (ONDP) under the new Office of Product Quality (OPQ) at CDER/ FDA supporting Gastroenterology, Hepatology & Nutrition and Dermatology and Dentistry therapeutic areas for both new and generic drug applications. At his current position, he oversees review activities of various dosage forms and participates in various key regulatory decision-making processes. He is the member of various working groups within CDER/FDA including the Transdermal Working Group. He is also an FDA-USP liaison of the Dosage Form Expert Committee. He is an avid speaker and coordinated short courses/symposiums in various national and international meetings on the regulatory aspects of different dosage forms. Beside several publications in different peer reviewed scientific journals, he is also the principal editor of four scientific books in the Marcel and Dekker series.

Stella Grosser, Ph.D.
Director at Division of Biometrics 8
CDER | FDA

Stella Grosser is Director, Division of Biometrics 8 in the Office of Biostatistics, CDER. This division provides statistical support to the Office of Generic Drugs. She has been at the FDA for 21 years, beginning as a statistical reviewer for new drug products and serving as a team leader before assuming her current position. Dr. Grosser received her PhD in biostatistics from UCLA and spent several years there afterwards as an assistant professor in the School of Public Health.

Sam H. Haidar, Ph.D., R.Ph.
Senior Science Advisor at Office of Study Integrity and Surveillance
FDA

Dr. Haidar is currently Senior Science Advisor, in the Office of Study Integrity and Surveillance, US FDA. He received a B.S. degree in Biology from Virginia Commonwealth University, a B.S. in Pharmacy from University of Maryland Baltimore (UMB), and Ph.D. degree in Pharmaceutical Sciences (UMB). Previously, Dr. Haidar held the positions of Branch Chief, Bioequivalence (BE) and GLP Branch; Deputy Director and Acting Director for the Division of Generic Drugs BE Evaluation. Other positions include Lead Pharmacologist, Office of Generic Drugs; Pharmacometrics Scientist and Clinical Pharmacology Reviewer in the Office of Clinical

Pharmacology and Biopharmaceutics. Dr. Haidar has served as Project Officer for FDA-funded research projects impacting policies and recommendations. Examples include Highly Variable Drugs: Scaled Average Bioequivalence, Impact of Excipients on BE of BCS Class 3 Drugs and use of neural networks in Pharmacokinetics and Pharmacodynamics modeling. His research activities and collaborations produced over thirty publications and a book chapter. Additionally, Dr. Haidar has represented the FDA in numerous national and international conferences, as well as in a scientist-exchange program with the Medical Products Agency in Sweden.

John Heaney, B.S.
Quality Manager and Application Specialist
Quality Lab Accessories, Telford, PA

John Heaney currently serves a dual role at Quality Lab Accessories as both the Quality Manager and Application Specialist. He began his career in the industry with Hanson Research (now Teledyne Hanson) as a field service engineer providing installation, qualification, maintenance, and technical support for diffusion and dissolution equipment. He was later transferred to the engineering team as his direct customer experience and expertise with common issues provided valuable insight into the development of new equipment including the Phoenix Dry Heat Systems. He later served at PermeGear in the role of Research and Technical specialist providing the same expertise as well as developing methods to test customer products. John began his work on the USP 1724 expert panel with Hanson Research and continued with PermeGear. He was a significant contributor to the equipment sections for the vertical diffusion cells, immersion cells, and flow through cells.

Xiaojian Jiang, Ph.D.
Deputy Director at Division of Bioequivalence II
Office of Bioequivalence
CDER | RSR | FDA

Dr. Xiaojian Jiang is currently the Deputy Director for the Division of Bioequivalence II, Office of Bioequivalence. The Division of Bioequivalence is responsible for the review of bioequivalence studies (with pharmacokinetic endpoint) submitted to support approved of ANDAs.

Dr. Xiaojian Jiang received her Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore. She joined the Division of Bioequivalence in 2003 as a pharmacologist reviewer. During her tenure in the FDA, Dr. Jiang made significant contributions to the approval and regulation of generic locally acting GI drug products, including vancomycin, mesalamine and orlistat. She is the principle investigator on a CDER RSR project, and is an active member on multiple FDA committees and working groups. Over the past 18 years, she has received numerous awards and honors from CDER and FDA for her dedication and

accomplishment as a scientist, reviewer, and leader. She has presented and published on a range of complex regulatory, scientific issues including BE approaches for locally acting drug products, highly variable drug products, in vitro dissolution testing, and in vitro BE approaches for nasal spray products.

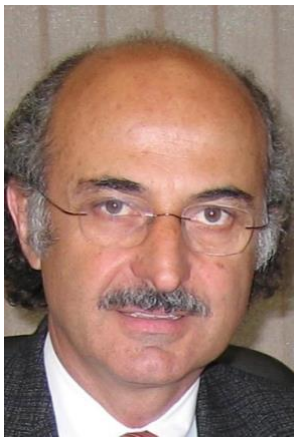
Amanda Jones, Ph.D.
Lead Pharmacologist
DBI | OB | OGD | FDA

Dr. Amanda Jones is a Lead Pharmacologist in the Division of Bioequivalence I (DBI), Office of Bioequivalence (OB), Office of Generic Drugs (OGD). In this role, she leads a team of pharmacologists assessing the *in vivo* and *in vitro* bioequivalence of various dosage forms of generic products. She is also involved in addressing controlled correspondences and pre-ANDA meeting packages, and development/revision of general guidances. Prior to joining the FDA in 2014, Dr. Jones was the Toxicologist Leader at GTx, Inc. (Memphis, TN) where she coordinated and monitored non-clinical safety pharmacology and toxicology studies and supervised phase I clinical trials. Dr. Jones received her Ph.D. in Pharmaceutics from The Ohio State University.

Abhishek Juluri, Ph.D.
Reviewer at Division of Bioequivalence III
Office of Bioequivalence
OGD | CDER | US FDA

Dr. Abhishek Juluri joined the FDA in 2019 and is currently a reviewer at the Division of Bioequivalence at the Office of Generic Drugs. He earned his bachelor's degree in pharmacy from Kakatiya University in 2009. He later earned his Ph.D. in Pharmaceutical Sciences from The University of Mississippi in 2014. He began his professional carrier as Senior Scientist at an early stage biotech company based in Akron, Ohio, where he worked on the development of novel drug delivery technology for Topical and Transdermal delivery of Macromolecules. Later he worked as a Principal Scientist at Tergus Pharma, a Topical CRO based in Durham, NC. His research interests include Topical and Transdermal drug product development.

Dr. Theo Kapanadze, Ph.D.
Chief Scientific Officer
DIteba Research Laboratories Inc.



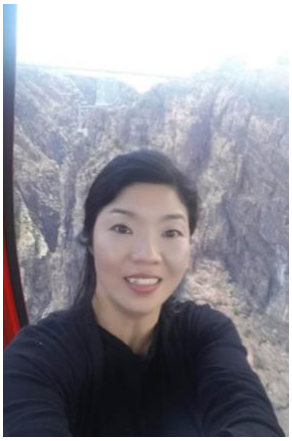
Theo Kapanadze, D.Sc., Ph.D., co-founder and Chief Scientific Officer of Diteba Research Laboratories Inc., has more than 30 years of analytical R & D Chemist and pharmaceutical industry experience.

Dr. Kapanadze capitalized on his years of experience evaluating drug product performance at leading analytical organizations to launch Diteba Research Lab, Inc. (now Diteba Laboratories Inc.) with a mission to provide quality analytical services to the Pharmaceutical, Biopharmaceutical and Nutraceutical industries. With the emergence of newer, alternative dosage forms over the last 15 years, he has become a well-recognized global leader in the development of topical drug products, providing expertise in the development and validation of performance tests used to evaluate the In Vitro absorption of drugs across skin and other membranes.

Usha Katragadda, Ph.D.
Bioequivalence Reviewer
Division of Bioequivalence III
OGD |CDER | FDA

Usha Katragadda serves as a Bioequivalence Reviewer in the Office of Generic Drugs (OGD) located in the Center for Drug Evaluation and Research (CDER). Usha Katragadda began her service with FDA in 2014. Prior to joining OGD, she conducted one year of post-doctoral training at the Division of Product Quality Research/CDER/FDA. Dr. Katragadda has earned a Doctor of Philosophy degree in Pharmaceutical Sciences from Mercer University, Atlanta, GA. She had earned a Master of Science degree in Chemistry from University of Dayton, Dayton, OH.

Juhyun Kim, Ph.D.
Bioequivalence Reviewer
Division of Bioequivalence III
OGD |CDER | FDA



Juhyun Kim serves as a Bioequivalence Reviewer in the Office of Generic Drugs (OGD). Juhyun Kim began her service with FDA in 2014. Prior to joining OGD, she worked at GTx Inc (Memphis, TN) for drug metabolism and pharmacokinetics. While she worked at GTx Inc, she also taught a graduate course in mass spectrometry as an adjunct professor at University of Tennessee Health Science Center. Juhyun received her Ph.D. in Pharmaceutical Science from the Ohio State University.

Luke Lee, I.D., M.E (Industrial Designer / Mechanical Engineer)
President / CEO
Logan Instruments Corp. (Somerset, New Jersey)

Luke Lee is CEO, President, Chief Designing Engineer of Logan Instruments Corp. currently working on laboratory Coating and Drying system for transdermal patches, new generation of USP 4 apparatus system for drug permeation and IVIVC studies. He has over 40 years experience in the tablets dissolution systems and 35 years experience in Transdermal diffusion cell apparatus. Luke Lee is the proud owner of over 70 design patents in the USA and China.His publication of Dissolution Technology Handbook – Fundamental Application of the Dissolution Testing in Pharmaceutical R & D will be published in January 2022.
Luke Lee graduated from Tatung Institute of technology, and then he got his degree from Pratt Institute graduated school for Industrial Design. Later, He studied in Columbia University, while there; he designed the DNA & RNA sequencers. Luke Lee also designed Automated Dissolution IVIVC equipment, the projects lead by late Prof. Arnold Beckett.

Paul A. Lehman, M.Sc.
Vice President
QPS LLC.

Paul Lehman joined QPS in 2013 as Vice President and Head of Dermal and Transdermal Research Services. Prior to joining QPS, Mr. Lehman held senior positions at PRACS Institute, Cetero Research, DermTech International, DermPharm, Inc. and the National Center for Toxicological Research (FDA). He has also held academic positions at North Dakota State University, University of Arkansas for Medical Sciences, and at University of Washington in Seattle. Mr. Lehman is a recognized expert on *in vitro* and *in vivo* percutaneous absorption pharmacokinetics, and dermal and transdermal bioavailability and bioequivalence. His bibliography currently includes 51 published manuscripts, 6 book chapters, and over 130 poster and lecture presentations. Mr. Lehman has been an integral partner with Dr. Thomas Franz (innovator of the Franz Diffusion Cell) since 1979, developing and validating *in vitro* and *in vivo* models for topical and transdermal formulations, and promoting alternative methods for generic bioequivalence assessments. Mr. Lehman received his BA and BBA at Incarnate Word College, San Antonio, TX, and his MSc in Pharmaceutics at the University of Washington in Seattle.

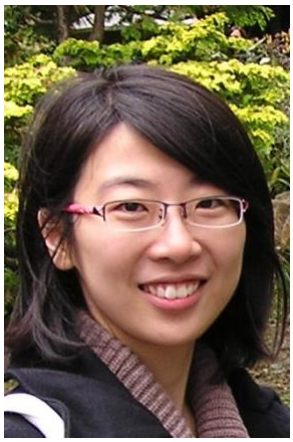
Jon Lenn, Ph.D.
Chief Scientific Officer
MedPharm

Jon Lenn is the Chief Scientific Officer at MedPharm, where he has direct responsibility for MedPharm's global research and development and is based out of its facility in Durham, North Carolina.
Since founding MedPharm's US operations in 2015, he has led the development of cutting-edge biological models, novel test systems, and the use of automation and robotics to streamline and enhance the drug development process. He has over 19 years' experience within the Pharmaceutical industry developing topical and transdermal medications from early discovery through development and into post-marketing support with companies such as Connetics, Stiefel and GlaxoSmithKline where he was directly involved with the development and approval of 8 marketed products.
Jon has spent the last several years in the development, optimization, qualification, and validation of novel biological models and testing tools to support the development of high-quality medicines for topical and transdermals (including skin, nail, airways, mucosal membranes and the eye). He received his PhD in Pharmaceutics on the topical delivery of macromolecules from the University of Reading

Markham C. Luke MD, Ph.D., F.A.A.D.
Director and Supervisory Physician (Dermatology)
Division of Therapeutic Performance I
ORS | OGD | CDER | US FDA

Markham C. Luke, MD, PhD, FAAD, serves as FDA Supervisory Physician (Dermatology) and Director of the Division of Therapeutic Performance 1 (DTP1) in the Office of Research and Standards, Office of Generic Drugs at FDA. DTP1 is responsible for facilitating pre-application development of generic drugs by conducting and promoting regulatory science research to establish standards to ensure therapeutic equivalence of new generic drug products.
Markham has an MD and a PhD in Pharmacology from Johns Hopkins University and completed his dermatology residency and fellowship at Washington University, St. Louis, MO and the National Institutes of Health, Bethesda, MD. Markham serves as Associate Professor in Dermatology at the Uniformed Services University of the Health Sciences, Bethesda, MD. Markham has research interests in dermatopharmacology, clinical pharmacology, clinical study design and endpoints assessment (including patient-reported outcomes) for medical, surgical, and aesthetic products and serves as consultant dermatologist to various parts of FDA. Markham has been at FDA since 1998 serving various roles, including as the Lead Medical Officer for dermatology drugs, Chief Medical Officer and Deputy Director for the Office of Device Evaluation in the Center for Devices and Radiologic Health, and as Acting Director for

Cosmetics in the Center for Food Safety and Applied Nutrition. In each of these roles including his current one in OGD, Markham has been involved in programs and initiatives dealing with product innovation as related to public health for our nation.



Tian Ma, Ph.D.
Bioequivalence Reviewer
OB | OGD | CDER | FDA

Dr. Tian Ma is a bioequivalence reviewer within the Division of Bioequivalence I in the Office of Bioequivalence. Prior to joining the FDA, Dr. Ma was a postdoctoral fellow in Dartmouth College. She obtained her B.Sc. in Pharmacology from the University of Toronto, Canada, and her Ph.D. in Pharmacology from Dartmouth College.

Howard Maibach, M.D.
Dermatologist
UCSF Health

Dr. Howard Maibach is a dermatologist with expertise in treating contact dermatitis (a rash caused by touching an irritating substance) and occupational dermatitis (a rash resulting from workplace exposure to an irritating substance). His specialties include allergic skin disorders and skin conditions caused by exposure to toxic substances. He also has an interest in dermatopharmacology, the study of medications for skin disorders.
Maibach earned his medical degree from Tulane University School of Medicine. He completed a residency as well as a fellowship in dermatology at the Hospital of the University of Pennsylvania.
Maibach has served on the editorial boards of more than 30 scientific journals. He is a member of 19 professional societies, including the American Academy of Dermatology, San Francisco Dermatological Society and International Commission on Occupational Health.

Archana A. Manerikar Pharm.D., M.S.
Bioequivalence Assessor Division of Bioequivalence
OB | OGD | CDER | FDA

Archana Manerikar serves as a Bioequivalence Assessor in the Office of Generic Drugs (OGD) located in the Center for Drug Evaluation and Research (CDER). She is responsible for the assessment of clinical pharmacology, bioequivalence, and dissolution data submitted by pharmaceutical firms. Archana Manerikar joined FDA as an ORISE fellow in the Office of Clinical Pharmacology (OCP) and later joined OGD in 2017. Prior to joining the FDA, Dr. Manerikar earned her Pharm.D. and M.S. in Pharmacometrics concurrently from the University of Maryland, Baltimore.

Margareth R. C. Marques, M. Sc., Ph.D.
Principal Scientist
United States Pharmacopeia

Dr. Margareth R. C. Marques is currently Principal Scientist at USP, where she manages several documentary standards on dissolution, disintegration, drug release, ophthalmic products and products applied to the skin. In addition, she manages the databases on reagents, chromatographic columns and dissolution/disintegration tests. She has a Bachelor's degree in Pharmacy, a M.Sc. in Pharmacy, both by the University of Sao Paulo, Brazil, and a Ph.D. in Analytical Chemistry by the State University of Campinas, Brazil. She has more than 20 years of experience in Quality Control and Quality Assurance both for active pharmaceutical ingredients as well as for pharmaceutical dosage forms.

Bozena Michniak-Kohn, Ph.D.
Professor of Pharmaceutical Sciences
Rutgers University

Dr. Bozena B. Michniak-Kohn is a tenured Professor of Pharmaceutics at the Ernest Mario School of Pharmacy, and Founder /Director of the Center for Dermal Research CDR at Rutgers, The State University of New Jersey, Piscataway, NJ. Her main focus is topical, transdermal and buccal drug delivery. Dr. Michniak-Kohn has over 40 years of experience in the design & optimization of topically applied formulations and transdermal patches. Dr. Michniak-Kohn received her B. Sc. (Honors) in Pharmacy and Ph.D. in Pharmacology from the U.K. Dr. Michniak-Kohn has directed over 58 Ph.D. and Masters students and the work resulted in about 170 peer-reviewed manuscripts, 470 abstracts, and 41 books and book chapters. She is a member of 10 journal editorial boards, several scientific advisory boards, member of Board of Trustees at TRI

Princeton and is a reviewer for over 50 pharmaceutical and drug delivery journals. For this work she was awarded Fellow status of the American Association of Pharmaceutical Scientists (AAPS) in 2008. Websites: www.centerfordermalresearch.org, and www.michniaklab.org.

Narasimha Murthy, Ph.D.
Founder/Director
Institute for Drug Delivery and Biomedical Research

Dr.Murthy is the Founder-Director of a non-profit research organization, Institute for Drug Delivery and Biomedical Research in Bangalore, India (www.IDBresearch.com). He is also the Chief Scientific Officer of the contract research company, Topical Products testing LLC, Oxford, MS. He was a former Professor at the University of Mississippi for 15 years.
Transcutaneous drug delivery is one of the main areas of Dr.Murthy's research. His research programs are funded by NIH, USFDA and Pharmaceutical companies. He has published over 100 research papers and presented over 200 scientific posters in various national and international scientific meetings. He has authored two books and over fifteen book chapters. He is serving on the Editorial Board of several journals including AAPS PharmSci Tech, DDIP and J Pharm.Sci.
Dr.Murthy has received several awards such as New Investigator award and Cumberland Researcher of the year from University of Mississippi, Global Indus Technovator award from MIT, Endowed Chair for Research at the Ohio Northern University and he was inducted as the Fellow of American Association of Pharmaceutical Scientists in 2017 and was honored with Distinguished Scientist award by American Association of Indian Pharmaceutical Scientists.

Anil K. Nair, Ph.D.
Team Leader, Division of Bioequivalence II
OGD | CDER | US FDA

Anil Nair joined the Division of Bioequivalence of Office of Generic drugs, US-FDA, after completing his post-doctoral training at Department of Biological Chemistry, University of Michigan Medical School, Ann Arbor. Dr. Nair has a Ph.D. in Biochemistry from University of Kerala, India. He joined US-FDA in 2008 as a primary reviewer in the Division of Bioequivalence, Office of Generic drugs. He has been serving as a Team Leader in the Division of Bioequivalence II since 2014 evaluating various types of pharmacokinetic/pharmacodynamic studies conducted to establish bioequivalence of Abbreviated New Drug Applications (ANDAs) for approval of potential new generic drug products.

Vijendra Nalamothu, Ph.D.
Chairman & CEO
Tergus Pharma

Dr. Vijendra Nalamothu is the Chairman & CEO of Tergus Pharma, a North Carolina-based CDMO which specializes in complete topical drug product development services, skin permeation, *in vitro* testing, and GMP manufacturing (up to 1500 kg per batch). Dr. Nalamothu earned his Ph.D. in Pharmaceutics from the University of the Science's Philadelphia College of Pharmacy. His efforts over the past 26 years in various dermatological companies have led to many commercial products in the market today. He has successfully taken Tergus Pharma from a small R&D facility to a 100,000 SFT commercial manufacturing facility with industry-leading capacities. His knowledge of the *unmet* needs in the Dermatology CDMO industry led to equipping Tergus Pharma with unique R&D capabilities such as Skin Biology and *In Vitro* Permeation (IVRT & IVPT) as well as Hormone and High Potent compound manufacturing at a commercial scale. Dr. Nalamothu draws from his exceptional background that combines scientific study with pragmatic, hands-on experience to solve R&D challenges and his ability to translate a concept into a commercial product. He has co/authored numerous publications and has patents for a few of his inventions. He serves as a member of various pharmaceutical associations as well as sits on the boards of various pharmaceutical companies. In his spare time, Dr. Nalamothu enjoys his quiet time with family, boating on Raleigh's Falls Lake.

Yuzhuo Pan, Ph.D.
Pharmacologist, Division of Bioequivalence II, Office of Bioequivalence
OGD | CDER | US FDA

Dr. Yuzhuo Pan currently is a pharmacologist of the Division of Bioequivalence II, Office of Bioequivalence, OGD. He serves as a divisional focal point for statistical analysis and modeling & simulation since 2014. Prior to that, he is a graduate of FDA commissioner fellow program (2012-2014) focus on PBPK. Dr. Pan obtained his Ph.D. and MBBS degree from Normal Bethune Medical school of Jilin University in China.

Ashvin Patel, Ph.D.
Director of Analytical Research and Business Development
Teledyne Hanson Research

Dr. Ashvin Patel is Director of Analytical Research and Business Development at Teledyne Hanson Research. Ashvin has been in pharmaceutical industry for over 25 years. He obtained Ph.D. in Chemistry from Veer Narmad South Gujarat University (India) in 1997. Prior to joining Teledyne, he held various positions with increasing responsibilities in large pharmaceuticals companies. He successfully led analytical laboratories to manage multiple research projects and team of talented scientists. His expertise and knowledge in Analytical chemistry helped many pharmaceutical companies to file ANDA and other regulatory submissions to obtain on time approval from FDA.

Hiren Patel, Ph.D.
Staff Fellow
Division of Bioequivalence II, Office of Bioequivalence
Office of Generic Drugs | CDER | U.S. FDA

Hiren Patel, Ph.D. is a bioequivalence assessor in the Division of Bioequivalence II within Office of Generic Drugs (OGD). Prior to joining FDA, Dr. Patel earned his M.S. and Ph.D. with specialization in Pharmacokinetics at Long Island University, Brooklyn, New York. At U.S. FDA, he is responsible for assessing the bioequivalence of the various dosage forms of generic drugs. He is the lead for the topical and transdermal drug products and the advanced techniques for demonstrating bioequivalence of such complex drug products within the Office of Bioequivalence. He is the co-chair for Bio-Equivalence Standards for Topicals Committee within OGD. He has also actively served as a consultant in the research initiatives which are the collaborative efforts of FDA and global research institutions pertaining to the topical and transdermal drug products funded through FDA. Dr. Patel is also actively involved in the review panel for the Product Specific Guidance for the generic topical drug products.

Joseph Payne, B.S.
VP of Quality and Compliance
Tergus Pharma LLC.

Mr. Payne has amassed more than 20 years of experience in Quality Systems. Starting as a Quality Control & Research Applications Scientist, then evolving to a Risk & Regulatory Compliance manager across a global network managing NDAs/ANDAs/ANADAs/BLAs, and into the last five years heading Corporate Quality and Regulatory functions for CDMOs which supported hundreds of clients. He has successfully delivered global CDMO quality leadership that supported multiple pharmaceutical facilities across the drug development lifecycle—from testing, manufacturing, and packaging, through the release of marketed drug substances and products. He is an active participant in the International Society of Pharmaceutical Engineers (ISPE), the Quality & Technical Committee of the Pharma BioPharma Outsourcing Association (PBOA) and the Parenteral Drug Association (PDA). Mr. Payne graduated from Hampden-Sydney College with a BS in Chemistry.

James Polli, Ph.D.
Co-Director
Center for Research on Complex Generics
CDER | US FDA
&
Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics University of Maryland

Dr. James E. Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption and formulation, involving laboratory and clinical research. He has served as advisor to 21 Ph.D. graduates. He is co-Director of the recently initiated Center for Research on Complex Generics, an FDA-funded collaborative agreement with the Agency. He is Director of the online MS in Regulatory Science program (www.pharmacy.umaryland.edu/regulatoryscience).

Kendall Powell, Ph.D.
Senior Director, Performance Testing and Bioanalytical
MedPharm, Ltd.

Kendall Powell joined MedPharm, Ltd., a leading CDMO specializing in topical and transdermal development, in 2016 as the Director of Bioanalytical for its newly opened site in Durham, NC. Kendall was instrumental in growing MedPharm's analytical and performance testing capabilities in the US and is now a Senior Director who oversees both the Performance Testing and Bioanalytical groups at MedPharm's Durham site. During his time at MedPharm he has helped the company successfully design, implement, and maintain a rigorous QMS to specifically support in vitro bioequivalence studies per both FDA and EMA draft guidances. Including his time at MedPharm, Kendall has over 20 years of CRO/CDMO industry experience working in both GLP-regulated spaces (bioanalysis) as well as pure research and development groups (DMPK, metabolomics) at a variety of companies in the Research Triangle Park area of NC. Kendall received his BS (Chemistry) and PhD (Analytical Chemistry) degrees from Duke University, also in Durham, NC; he can be quite annoying during college basketball season.

Tannaz Ramezanli, Pharm.D., Ph.D.
Pharmacologist
ORS | OGD | US FDA

Dr. Tannaz Ramezanli is a pharmacologist within the Office of Research and Standard (ORS) at Office of Generic Drugs (OGD) at the U.S. FDA. She specializes in topical and transdermal products. She is responsible for the development of product-specific bioequivalence guidances, reviewing and responding to controlled correspondences, citizen petitions, and Pre-ANDA meeting packages. She also serves as Project Officer for multiple regulatory science research initiatives related to development of bioequivalence standards for complex topical drug products through FDA-funded collaborations with research institutions around the world. She received her Ph.D. in Pharmaceutical Sciences from Rutgers University and her Pharm.D. from Tehran University of Medical Sciences.

Sam Raney, Ph.D.
Associate Director/Chief Scientific Advisor
ORS | OGD | FDA

Dr. Sam Raney is a thought leader in topical and transdermal drug products, with over 30 years of experience in skin research, producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, and serves on multiple expert committees and panels for the U.S. Pharmacopeia. He is the Associate Director for Science in the FDA's Office of Research and Standards, and serves as the Chief Scientific Advisor for topical product bioequivalence issues in FDA's Office of Generic Drugs. Dr. Raney holds a Bachelor's Degree in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

Elena Rantou, Ph.D.
Lead Mathematical Statistician
Division of Biometrics 8, Office of Biostatistics, Office of Translational Sciences
CDER | FDA

Elena joined the FDA in 2013. Her work and research interests focus on the evaluation of generic drugs and more specifically, the development of the statistical framework for assessing bioequivalence for topical dermatological products, as well as, the characterization and handling of outliers in replicate pharmacokinetic studies. She earned her PhD from American University in Washington DC. Prior to joining FDA Elena has worked in the academia and as a statistical consultant.

Leandro L. Santos, M.S.
Director, Clinical Research
Incyte Corporation

Leandro is currently Director, Clinical Research, at Incyte Corporation. He holds a double major in Pharmaceutical Sciences and Biochemistry from the University of Sao Paulo (Brazil) and a Master of Science in Analytical Chemistry from the University of North Carolina at Chapel Hill. He joined Incyte in 2019 as a clinical scientist with focus on late-stage development of drugs for treatment of inflammatory diseases after spending 14 years in Nonclinical Discovery and Development at Stiefel/GlaxoSmithKline and Dermavant, and has worked in different

areas of Rx and Cx dermal product development, including analytical, formulation, preformulation, DMPK, and drug delivery. He has led projects focused on various stages of development, as well as conceptualized and implemented tools used in in silico, in vitro and in vivo workflows. He has co-authored nonclinical sections of regulatory submissions, as well as patents and papers in peer-reviewed journals, and contributed to the development of several assets currently in clinical stage of development.

Anna Schwendeman, Ph. D.
Co-Director
Center for Research on Complex Generics (CRCG)
CDER | US FDA
&
William I Higuchi Collegiate Professor of Pharmacy
Associate Professor of Pharmaceutical Sciences
Biointerfaces Institute
College of Pharmacy
University of Michigan

Anna Schwendeman is William I Higuchi Collegiate Professor of Pharmacy and Associate Professor of Pharmaceutical Sciences at the University of Michigan. Her research focus is on optimization high-density lipoprotein (HDL) nanoparticles for treatment of atherosclerosis, sepsis and drug delivery purposes. In 2016, she co-founded a company EVOQ Therapeutics (www.evoqtherapeutics.com) focused on the use of HDL nanodiscs for delivery of personalized neoantigen cancer vaccines. Dr. Schwendeman received her BS from Moscow Institute of Physics and Technology and PhD in Pharmaceutics from The Ohio State University. Prior to starting her academic career in 2012, Dr. Schwendeman spent 12 years in pharmaceutical industry at Cerenis Therapeutics, Pfizer, and Esperion Therapeutics. She was involved in discovery and translation HDL drugs to clinical trials. She successfully submitted FDA INDs for seven different products including nanoparticles, liposome, recombinant proteins, peptides and small molecules. Her laboratory's research in regulatory sciences is focused on analytical characterization of liposomes, polymer microspheres, peptides and biosimilar products. She is co-director of FDA sponsored Center for Research in Complex Generics (http://www.complexgenerics.org). Dr. Schwendeman is an Associate Editor for *Nanomedicine NBM* and *Eur. J. Pharm and Biopharm*.

Vinod P. Shah, Ph.D., F.A.A.P.S., F.F.I.P.
Pharmaceutical Consultant
VPS Consulting, LLC.

Dr Shah is a Pharmaceutical Consultant; a member of Steering Committee of Non-Biological Complex Drugs (NBCD) hosted at Lygature in The Netherlands (2011-Present) and expert consultant with NDA Partners (2016 – Present). He received his Pharmacy degree with Gold Medal distinction from Madras University, India and Ph. D. in Pharmaceutical Chemistry from the University of California, San Francisco (UCSF).
Dr Shah worked at US FDA (Food and Drug Administration) from 1975-2005. At FDA he developed several Regulatory Guidances for Industry in the area of dissolution, SUPAC, bioanalytical method validation, topicals, bioequivalence and biopharmaceutics; and pioneered method development for in vitro drug release for semisolid dosage forms.
Dr Shah was Scientific Secretary (2003 – 2011) of International Pharmaceutical Federation (FIP); and Biopharmaceutics Consultant at USP (2005-2014). Dr Shah is author/co-author of over 330 scientific papers and is a co-editor of four books.
Dr Shah was the President of American Association of Pharmaceutical Scientists (AAPS) in 2003. He is a Fellow of AAPS and FIP. Dr Shah is a recipient of many FDA, National and International Awards.

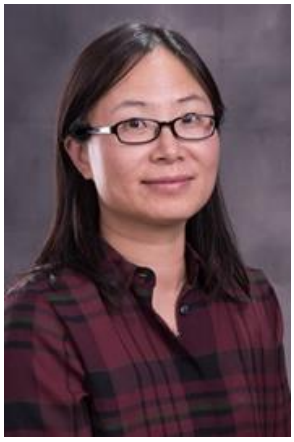
Audra Stinchcomb, Ph.D.
Professor of Pharmaceutical Sciences/ Co-Founder
University of Maryland/ F6 Pharma Inc.

Dr. Stinchcomb is Professor of Pharmaceutical Sciences, School of Pharmacy, University of Maryland, Baltimore. She is also currently the Chief Scientific Officer and Co-Founder of F6 Pharma Inc., a dermal product development company. She received her Bachelor's in Pharmacy from the University of Colorado, and a PhD in Pharmaceutics from the University of Michigan. She completed a postdoctoral fellowship at UCSF. She was a Professor at the University of Kentucky from 2001-11, and joined the faculty at UMB in November 2011. She is a Fellow of the American Association of Pharmaceutical Scientists. Dr. Stinchcomb's research interests span across many disciplines, including pharmaceutics, drug delivery, medicinal chemistry, neuroscience, dermatology, bioengineering, regulatory science, and translational research models.

Kailas Thakker, Pharm.D., M.S., Ph.D.
President
TopiKail Consulting

Kailas Thakker graduated from Institute of Chemical Technology in Mumbai with a degree in Pharmacy and then went on to earn Masters in Pharmaceutical Sciences from Columbia University in New York and Doctor of Philosophy in Pharmaceutical Sciences from University of Kansas.
She worked at United States Pharmacopeia for 12 years and then went on to head Analytical Department at small, virtual, venture backed biotech company in RTP Area.
In 1994, She founded Analytical Solutions with a vision to provide high quality analytical services to Pharmaceutical Industry. Working with regulatory, compendial and industry leaders, she worked towards developing and improving In Vitro Release Test (IVRT) for topical dosage forms emerging as a premier service provider for developing IVRT. In 2012, Analytical Solutions was rebranded to Tergus Pharma with a vision to expand the service base by partnering with Dr. Vijendra Nalamothu. Today Tergus Pharma is a world known service provider for topical product development. After retiring from active duty at Tergus Pharma in 2018, Kailas continued to advise and assist in developing In Vitro Sciences at Tergus Pharma as Confounder Emeritus. In 2021, Kailas launched her consulting firm, TopiKail Consulting. As a president of TopiKail Consulting, Kailas continues to serve the pharmaceutical industry with her knowledge of in vitro sciences as well as business strategy for startup CROs. Kailas also serves as a chair of USP's expert panel for topical and transdermal dosage forms. Kailas's interests are in developing and standardizing in vitro sciences for topical as well as other novel dosage forms where same principles are applicable.

Rong Wang, Ph.D., Pharm.D.
Acting Associate Director, Division of Bioequivalence I (DBI), Office of Bioequivalence (OB)
OGD|CDER|FDA



Dr. Rong Wang is currently the acting associate director in the Division of Bioequivalence I, Office of Bioequivalence, Office of Generic Drugs. Dr. Wang has worked as a pharmacologist in Office of Bioequivalence (OB) for over ten years and accrued extensive knowledge and experiences in generic drug bioequivalence evaluation. She supervises DBI scientists in conducting bioequivalence assessment of abbreviated new drug applications (ANDAs) and addressing inquiries submitted by applicants through control correspondences and meetings such as post complete response meetings and mid-cycle meetings. Dr. Wang also actively participates in various working groups within the Agency where she has contributed her expertise and experiences in revising or developing general guidance for ANDA submission and establishing work process for ANDA assessment.

Dr. Wang received her undergraduate degree in pharmacy from Shanghai Medical University and her Ph.D. in Microbial and Biochemical Pharmaceutical Science from Institute of Medicinal Biotechnology, Chinese Academy of Medical Science & Peking Union Medical College in China. Dr. Wang also earned her Pharm.D. from University of Florida. Prior to joining FDA, she had worked as a clinical pharmacist at University of California San Francisco Medical Center.

Kevin S. Warner, Ph.D.
Vice President, Pharmaceutical Department
Alucent Biomedical, Inc.

Dr. Kevin Warner has over 15 years of experience in topical product development, including formulation and manufacturing process development. He has worked in formulation and manufacturing process development roles of increasing responsibility throughout his career. He is also a member of USP General Chapters- Dosage Forms Expert Committee. As part of his responsibilities on the Dosage Forms Expert Committee, he is chair of USP < 3> subcommittee and a member of the USP < 1724> subcommittee. He has a bachelor's degree in chemistry from Brigham Young University, and a Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from the University of Utah.

Andrew Wilt
President
PermeGear, Inc.

In 1973 Andrew Wilt founded Quality Machining, a job shop that made precision machine parts. In the early 1980s Quality Machining became AMIE Systems which manufactured magnetic stirrers and accessories for Crown Glass Company's lines of blown glass diffusion cells. In 1994, AMIE Systems became PermeGear. Today, PermeGear is recognized as a leader in the diffusion cell industry. Every year researchers purchase thousands of Franz Cells, Side-Bi-Side Cells, and PermeGear's flow type In-Line Cells. Custom diffusion cells of all kinds are a PermeGear specialty. From high school science projects to startup and long established pharma companies, PermeGear is the standard for your lab.

Yang Yang, Ph.D.
Principal Investigator, CMC Reviewer, Team Lead
OTR | DPQ | OPQ | FDA

Dr. Yang Yang is a staff fellow at the FDA's Office of Pharmaceutical Quality, Office of Testing and Research, Division of Product Quality Research. She is a Principal Investigator, CMC reviewer, and the team lead of FDA *in vitro* sunscreen studies. She graduated from Peking University College of Pharmacy (Beijing, China) with a bachelor's degree in Pharmacy and a Master's degree in Molecular Pharmacology. She obtained her PhD in Biopharmaceutical Sciences from the University of Illinois at Chicago. Her research emphasizes on the quality of complex drug products including topical and transdermal drug delivery systems, abuse-deterrent opioid formulations, and other extended release dosage forms. She also participated in numerous grant proposal reviews and provided professional trainings to FDA employees and Postdoctoral fellows.

Cristina Yen, B.S.
Senior Manager, IVRT
Tergus Pharma

Cristina Yen serves as Senior Manager of the In Vitro Release Testing Department of Tergus Pharma. Cristina leads a team of 8 analyst in development and validation of IVRT methods to support generic drug development, post-approval manufacturing changes in compliance with SUPAC-SS guidance, and BA/BE waivers. Cristina has 12 years of experience in the pharmaceutical field, five of which have been in development and validations of IVRT methods for many molecules and formulations. Cristina has developed training curriculum in theory and technique for the IVRT team and other efficiencies to ensure quality and delivery.

Ahmed Zidan, Ph.D.
Senior Pharmacologist Staff, Office of Testing and Research/Office of Pharmaceutical Quality
CDER | FDA

Dr. Ahmed Zidan is a senior pharmacologist staff in the CDER/OPQ. Ahmed joined FDA in 2005 and has a Ph.D. in pharmaceutical sciences in Zagazig University in collaboration with Howard university, USA. Dr Zidan leads the topical and transdermal drug products laboratories of DPQR in OPQ and provides hands-on trainings to reviewers on various topics, including 3D printing, preformulation consideration for development of oral drug products, transdermal delivery systems and in vitro release and permeation testing of pharmaceuticals. Dr. Zidan is a member

of the Transdermal Working Groups of CDER and additive manufacturing and chaired several scientific lab events at CDER. Dr. Zidan is also an editorial board member of several pharmaceutical journals and published over 100 peer-reviewed articles and book chapters.