FDA Commissioner's Fellowship Program

Class of 2016

FDA Commissioner's Fellowship Program

2016 Fellows

FDA Commissioner's Fellowship Program

2016 Preceptors

FDA Commissioner's Fellowship Program

2016 Preceptors and Fellows Projects listed by Regulatory Science Priority Area

Modernize Toxicology to Enhance Product Safety (1)

Sherry A. Ferguson (Fellow: Christopher L. Moore)

Stimulate Innovation in Clinical Trials and Personalized Medicine to Improve Product Development and Patient Outcomes (4)

Christopher Leptak (Fellows: Abena Agyeman & Carolina Panico)
Azadeh Shoaibi (Fellow: Joyce Obidi)
Wenming Xiao (Fellow: Qianghua Xia**)**

Support New Approaches to Improve Product Manufacturing and Quality (2)

Christine Karbiwnyk (Fellow: Stephanie Cole)
Mohammad Heidaran (Fellow: Tal Hila Salz)

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies (3)

Michelle Moore (Fellow: Kayleigh MacMaster)
Becky Robinson, Carolyn Yong (Fellow: Zehra Tosun)
Thilak Mudalige (Fellow: Desiree Van Haute)

Implement a New Prevention-Focused Food Safety System to Protect Public Health (4)

Yi Chen (Fellow: Fengmin Li)
Nakissa Sadrich (Fellow: Mi Sun Moon)
Sherri B. Turnipseed (Fellow: I-Lu Wu)
Donna-William-Hill (Fellow: Ashley Queen)

Strength Social and Behavioral Science to help Consumers and Professionals Make Informed Decisions about Regulated Products (2)

Nicole Borek (Fellow: Rachel Zamoiski)
Robert Sokilic and Ke Liu (Fellow: Ihid Carniero Leao)

FDA Commissioner's Fellowship Program

2016 Preceptors and Fellows by Center

CBER

Preceptors	Fellows
Azadeh Shoaibi	Joyce Odibi
Mohammad Heideran	Tal Hila Salz
Becky Robinson	Zehra Tosun
Carolyn Yong	

CDER

Preceptors	Fellows
Christopher Leptak	Abena Agyeman
Christopher Leptak	Carolina Panico

CFSAN

Preceptors	Fellow
Yang Chen	Fengmin Li
Nakissa Sadrieh	Mi Sun Moon

CTP

Preceptors	Fellows
Nicolette Borek	Rachel Zamoiski

NCTR

Preceptors	Fellows
Wenming Xiao	Quanghua Xia

ORA

Preceptors	Fellows
Christine Karbiwnyk	Stephanie Cole
Ke Liu	Ihid Carneiro Leao
Maichelle Moore	Kayleigh MacMaster
	Christopher Moore
	I-Lu Wu
Robert Sokilic	Ihid Carneiro Leao

FDA Commissioner's Fellowship Program

2016 Fellows

Abena Agyeman, Ph.D.

Division/Office: CDER/OND Immediate Office

Preceptor: Christopher Leptak, M.D., Ph.D.

Scientific and Professional Background

2000-2005: University of Auckland, BSc

2002-2004: Smith College, BA

2005-2011: Johns Hopkins School of Public Health, PhD

2011-2016: The University of Chicago, Post Doc

Research Interests

Dr. Agyeman has used her molecular biology and biochemistry expertise to develop pharmacodynamic and predictive biomarkers for breast cancer prevention and treatment. Working closely with multidisciplinary teams, she then designed clinical trials to analyze these biomarkers. Currently, Dr. Agyeman is interested in developing, implementing, and communicating policies and programs to enhance the regulatory review process for oncology products at the FDA.

CFP Project Summary

Project title: *Surrogate Endpoints and Drug Approval*

FDA Scientific Priority Area the project falls under: Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes

Description: To expedite patients' access to important treatments for serious conditions, the FDA has a long history of using surrogate endpoints (SEs) to promote drug development. SEs are biomarkers that predict a clinical benefit, but are not themselves a measure of clinical benefit (examples include: blood pressure, tumor response rate, hemoglobin A1C and HIV viral load). SEs can be used for both traditional and accelerated approval, where for the latter they are "reasonably likely to predict a clinical benefit", with the data to confirm clinical benefit provided as part of post-marketing requirements. The goal of this project is to look at how SEs have been used in drug approval, both accelerated and traditional, to classify these SEs using the current BEST resource definitions, and to look more broadly for SEs that are included in existing guidance and other internal resources. The plan is to share this information with OND's review divisions and curate for both accuracy and completeness.

Ihid Carneiro Leao, M.D., Ph.D.

Center for Biologics Evaluation and Research

Preceptors: Robert Sokilic, M.D.. and Ke Liu, M.D., Ph.D.

Scientific and Professional Background

MD, Universidade Federal de Pernambuco, Brazil, 1990-1996

Internal Medicine Residency, Hospital Barao de Lucena, Pernambuco Brazil, 1997-1998

Staff Physician, Hospital Agamenon Magalhaes, Pernambuco Brazil, 1999-2000

PhD, Pharmacology and Molecular Sciences, Johns Hopkins School of Medicine, Baltimore, 2001-2005

Oncology Fellow, Johns Hopkins School of Medicine, Baltimore, 2006-2008

Master of Advanced Studies, Clinical Research, University of California, Davis, 2013-2015

Project Scientist, University of California, Davis, 2012-2017

Research Interests

I am a physician scientist, with medical training in Internal Medicine and research expertise in Infectious Disease and Immunology. Prior to joining the FDA, I worked on the pre-clinical and clinical development of antivirals and immunotherapies for cancer on the academic side. A central theme of my research is to understand disease pathogenesis and to apply this knowledge toward novel therapeutic approaches. My motivation for pursuing a research career was to make an impact in medical practice for diseases of unmet need. Patients are in a unique position to inform us on disease severity and on benefit-risk assessments of current and future treatments. My research at the FDA will focus on developing a systematic approach to accessing evidence and uncertainties for new therapies and on incorporating patient perspectives into medical and regulatory decisions.

CFP Project Summary

Project Title: *Decision-making model for Wiskott-Aldrich Syndrome*

FDA Regulatory Science Priority Area: *Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products*

Wiskott-Aldrich syndrome (WAS) is a rare immune deficiency with a wide range of clinical presentations. As with many rare diseases, single arm studies and expert opinions are used to inform treatment decisions. In addition, data on quality of life of patients that had chosen different treatment options for WAS is not available. Treatment decisions have significant impact on a patient's length and quality of life and some decisions preclude other options in the future. Quantitative decision analysis in this setting could be an important adjunct for medical decisions at the patient level, and regulatory decisions at the population level.

In order to develop a conceptual framework for decision-making in WAS, OTAT in partnership with OBE will develop a computational model as a means to facilitate the elicitation of informed patient and parent preferences. The first stage of the project is to create a decision analysis tool that captures the range of likely outcomes of available treatments. Simultaneously, OTAT has initiated a collaboration with the Primary Immune Deficiency Treatment Consortium (PIDTC) and with patient advocacy groups focused on WAS in order to empirically measure the quality of life of patients with WAS. This data will be used to refine the decision analysis model to focus on patient-centered outcomes. Finally, actual patient preferences will be elicited through collaboration with OBE and patient advocacy groups. This data will be used to create a novel tool useful in individual patient counselling during initial and ongoing therapy of WAS. Additionally, it will also guide the FDA on how to use patient preferences to inform regulatory decisions on therapies with potential for high benefit at the expense of high up-front risks.

Stephanie Cole, Ph.D.

Office of Regulatory Affairs (ORA)

Preceptor: Christine Karbiwnyk, Ph.D.

Scientific and Professional Background

2012-2016 Post-doctoral Researcher, University of Maryland, College Park

2007-2012 Ph.D., Molecular, Cell and Developmental Biology, University of California, Los Angeles

2003-2007 B.S., Biological Sciences, University of Maryland, College Park

Research Interests

Dr. Cole's research interests are in host-pathogen interactions and how those interactions can lead to disease. As a post-doctoral researcher at the University of Maryland, she studied bacterial components that are required for biofilm formation in vivo during catheter-associated urinary tract infection. She discovered that host factors, like urine, have an impact on bacterial biofilm development. As a graduate student, she studied the interaction between a fungal pathogen that caused wilt disease in a plant host.

CFP Project Summary

Project Title: *Identifying molds and yeasts using matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF MS)*

Regulatory Science Priority Area: Support New Approaches to Improve Product Manufacturing and Quality

Fungi are found almost ubiquitously in the environment: soil, water and air. In recent years, the number of human fungal infections has increased in part due to advances in modern medicine, such as the wide use of medical hardware (central lines), in addition to, organ donation and chemotherapy treatments that have increased the number of immunocompromised individuals. Furthermore, drug manufacturers and compounding facilities have recently had issues with decontamination of fungi in sterile rooms, which have led to several recalls of fungal contaminated medicines and medical devices. There is a need to quickly identify fungi that cause outbreaks so that affected individuals receive proper medical treatment and contaminated products are recalled. The current methods available for identifying fungi are either too time consuming or too expensive. Therefore, the aim of this project is to develop a MALDI-TOF MS based method to quickly identify isolated fungi.

Fengmin Li Ph.D.

Division of Microbiology

Office of Regulatory Science, CFSAN

Preceptor: Yi Chen, Ph.D.

Scientific and Professional Background

Oct. 2016-present FDA commissioner's fellow

Nov. 2013-Oct. 2016 Research fellow, Liver Disease Branch, NIDDK/NIH

Oct. 2011-Nov. 2013 Postdoc fellow, Liver Disease Branch, NIDDK, NIDDK/NIH

Aug. 2005-May 2011 Ph.D. in molecular physiology, Department of physiology and biophysics, Georgetown University

Sep. 2000-Jul. 2003 M.S. in Microbiology, Northeast Normal University, China

Research Interests

Prior to joining the FDA, her research interests spanned a wide range of topics in microbiology, cell biology and molecular physiology. She had worked on the isolation, purification, and cultivation of cellulose-decomposing bacterium strain which was aimed for fiber digestion. Then, her research was focused on diverse signaling pathways well known to be involved in cancer or/and metabolism syndrome diseases, e.g., GPCR, insulin signaling pathway, TGFβ signaling pathway and hippo signaling pathway. Specifically, she investigated gene regulation, protein interaction, expression and function in different signaling pathways and their cross-talking in different cells lines and animal models.

CFP Project Summary

Project title: *Development and validation of environmental testing methods for Listeria monocytogenes (L. monocytogenes)*

FDA Scientific Priority Area: Implement a New Prevention-Focused Food Safety System to Protect Public Health

Recently, *L. monocytogenes* has been implicated in major outbreaks and recalls which were associated with contaminated cantaloupes in 2011, contaminated cheeses and stone fruits in 2014, contaminated caramel apples in 2014-2015, and contaminated packaged salads in 2016. These incidents emphasize the importance of nationwide testing and monitoring of *L. monocytogenes* in food commodities as well as in the food processing, packing and retail environment. Therefore, the goal of this project is to optimize environmental testing procedures to help identify source of contamination during outbreak, which will eventually contribute to the development of effective and preventive control measures to ensure the safety of final food products. This project is proposed to: 1. Evaluate a variety of sampling devices made of different materials that have been commercialized in the past few years. 2. Incorporate rapid molecular methods into environmental testing. 3. Validate several novel neutralizing broths against commonly used D/E broth. 4. Evaluate additional enrichment broths and selective agars for their ability to isolate and detect *L. monocytogenes* in complex environmental samples with high level of background microflora.

Kayleigh MacMaster, Ph.D.

Applied Technology Center, Pacific Regional Laboratory Northwest

Office of Regulatory Affairs (ORA)

Preceptor: Michelle Moore, Ph.D.

Scientific and Professional Background

2015-2016 Postdoctoral Fellow, Department of Molecular Genetics, Biochemistry and Microbiology, University of Cincinnati, Cincinnati, OH

2008-2015 PhD. Microbiology, University of Cincinnati, Cincinnati, OH

2004-2008 B.S. Biochemistry Nazareth College, Rochester, NY

Research Interests

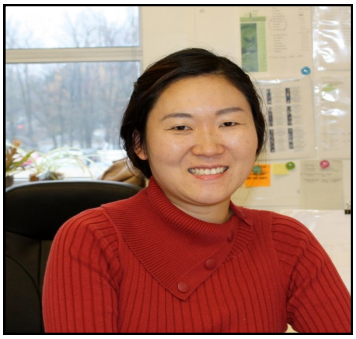
Kayleigh is interested in bacterial pathogens and food safety. Her previous work focused on the bacterial toxin, Shiga toxin, from Shiga toxin-producing *E. coli* (STEC). She characterized interactions of the toxin with both epithelial and endothelial cells to better understand how the toxin can lead to cellular death and severe disease.

CFP Project Summary

Project Title: *Comparison of Salmonella WGS serotyping methods with bead-based molecular serotyping methods in Salmonella isolated from food and environmental samples*

FDA Regulatory Science Priority Area: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

Salmonella serotyping is a subtyping method that has proven invaluable in differentiating isolates for public health purposes such as surveillance and outbreak investigations. Over 2500 *Salmonella* serovars (or serotypes) have been identified. In traditional serotyping the production and quality control of the hundreds of antisera required to generate these serovars are difficult, time consuming and expensive. In recent years new technologies have been developed to determine serotype by molecular methods and using whole genome sequencing (WGS) data. The goal of this project is to evaluate WGS serotyping by two web-based tools (SeqSero and SISTR), and compare them with Salmonella molecular serotyping (SMS) and traditional serotyping. Whole genome sequencing is now done on all *Salmonella* isolated by FDA regulatory laboratories. The results of this study will show if genome based serotyping methods are comparable to traditional and molecular methods, and if the results can be obtained faster than traditional methods, which can take 3 to 5 days or more for full determination of the serovar.



Mi Sun Moon, Ph.D.

Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Preceptor: Nakissa Sadrieh, Ph.D.

Scientific and Professional Background

2012-2016 Postdoctoral Fellow, Liver Diseases Branch, NIDDK, NIH
2010-2012 Postdoctoral Fellow, Microbiology and Immunology, Penn State College of Medicine
2004-2010 Ph.D., Microbiology and Immunology, Penn State College of Medicine
2003-2004 Visiting Research Associate, University of Pittsburgh School of Medicine
1997-1999 M.S., Life Science, Sogang University, Seoul, South Korea
1993-1997 B.S., Life Science, Sogang University, Seoul, South Korea

Research Interests

Dr. Moon's research interest is to understand the relationships between microorganisms and host immune responses to address a question how they contribute to disease progression. Previously she conducted translational research focusing on the role of gut microbiome and host immune responses with a goal to discover biomarkers of liver disease progression in patients with hepatitis C infection. Currently, she is interested in expanding her scientific expertise to develop regulations and policies in microbiological analysis methods in cosmetic products.

CFP Project Summary

Project Title: *Development of Guidelines and Policies for Microbiological Analysis Methods in Cosmetic Products*

FDA Regulatory Science Priority Area: Implement a New Prevention-Focused Food Safety System to Protect Public Health

Microbiological safety in cosmetics is a key strategic initiative of the Cosmetic Safety program, which is directly linked to FDA's public health mission to protect and improve public health. As an effort on cosmetic microbiological safety, FDA has presented its preferred laboratory procedures for microbiological analyses in the *Bacteriological Analytical Manual* (BAM), Chapter 23, which is solely dedicated in cosmetics and cosmetic ingredients. However, the BAM, Chapter 23 has not served well as an enforcement policy for industry, which does not follow the BAM Chapter 23 unless specifically asked to comply it. The BAM, Chapter 23 needs to be updated and revised in response to dynamic changes in science and technology. Moreover, it needs to be harmonized with ISO17516, international guidance which is a widely accepted global standard for microbiological limits in cosmetics. The goal of this project is to improve and harmonize our microbiological analysis methods in cosmetic products and support the development of more focused policies and guidelines to manufacturers of cosmetic products.

Christopher L. Moore, Ph.D.

National Center for Toxicological Research (NCTR)

Division of Neurotoxicology

Preceptor: Sherry A. Ferguson, Ph.D.

Scientific and Professional Background

Education:

2015 Ph.D. Pharmacology, University of Arkansas for Medical Sciences

2010 M.S. Quality Assurance & Regulatory Affairs, Temple University School of Pharmacy

1994 B.S. Ecology & Evolutionary Biology, University of Arizona

Experience:

2015-2016 Postdoctoral Fellow, Radiology, University of Arkansas for Medical Sciences

2010-2015 Graduate Assistant, Pharmacology, University of Arkansas for Medical Sciences

2001-2009 Senior Associate Scientist, CNS Pharmacology, Pfizer Global R&D

1999-2001 Associate Scientist, Neuroscience Therapeutics, Parke-Davis Pharmaceuticals

Research Interests

Christopher is interested in multi-disciplinary approaches to pharmacological and toxicological risk-benefit assessment. His previous research focused on identifying a potential mechanism to account for a higher risk of stroke associated with beta-blocker therapy relative to other classes of anti-hypertensive drugs. Prior to his cardiovascular focus, he worked in pre-clinical psychotherapeutic drug discovery using behavioral pharmacology endpoints to assess the safety and efficacy of novel compounds.

CFP Project Summary

Project title: *Developmental neurotoxicity evaluation of inorganic arsenic exposure*

FDA Scientific Priority Area: Modernize Toxicology to Enhance Product Safety

Arsenic is a naturally occurring element found in food, water and the environment. Arsenic occurs in organic and inorganic forms with the inorganic form considered to be more toxic. The toxic effects of high levels of arsenic are well known and include cancer and cardiovascular toxicity. The level of arsenic normally found in food is not a concern for acute toxicity. However, there is a gap in knowledge about non-cancer health risks of low-level arsenic exposure during susceptible life stages such as infancy and childhood. We propose to study effects of low-level inorganic arsenic on brain development in rats exposed in-utero through infancy. The behavioral development, learning and memory ability and neurohistochemical profile of arsenic exposed rats will be evaluated. A non-clinical neurotoxicity profile of low-level arsenic exposure during the susceptible life stages of gestation and infancy could advance our ability to estimate risks from dietary source levels of arsenic on childhood development.

Joyce O. Obidi, Ph.D.

Immediate Office of Director

Office of Biostatistics and Epidemiology

Center for Biologics Evaluation and Research

Preceptor: Azadeh Shoaibi, Ph.D., MSH

Scientific & Professional Background

2001-2005	Bachelors of Science, Cornell University
2005-2012	PhD, Cellular and Molecular Medicine, Johns Hopkins University
2012-2014	Postdoctoral Fellow, Translational Oncology Medicine, MedImmune

Research Interests

Joyce Obidi's research background is in translational oncology research. Her doctoral research investigated the role of Notch signaling in cancer stem cells in Non-small cell lung carcinoma. After completing her dissertation, Dr. Obidi completed her post-doctoral research at MedImmune (Gaithersburg, MD), the global biologics R&D arm of AstraZeneca. She worked on developing assays that could be used to optimize new therapeutic strategies and personalized medicine which could aid in the stratification of cancer patients. Currently, Dr. Obidi's efforts at the FDA are directed toward understanding how to harness the information found in electronic health records to complement the FDA's post market surveillance activities.

CFP Project Summary

Project Title: *Advancing the Use of Electronic Health Records in Monitoring the Safety of Blood and Blood Products*

Regulatory Science Priority Area: Stimulate Innovation in Clinical Trials and Personalized Medicine to Improve Product Development and Patient Outcomes

The Food and Drug Administration (FDA) Amendments Act of 2007 required that the FDA develop a system to monitor and analyze the post-market risk of medical products including drugs, vaccines, and other biologics. The FDA established the Sentinel Initiative in 2009, a multiyear effort to build the system to evaluate safety of medical products with respect to health outcomes across large health insurance databases. Electronic health records contain a wealth of information; understanding and harnessing this data will aid in monitoring the safety of the U.S. blood supply. The goal of the proposed research is to explore electronic health records from Hospital Corporation of America (a new data partner to the Sentinel System) to understand how the data can be utilized to monitor adverse events related to exposure to blood products and blood components and to assist in monitoring the safety of the blood supply. This improved capability could inform FDA regulatory decisions and actions and ultimately impact public health.

Ashley Queen, Ph.D.

Office of Regulatory Affairs (ORA)
Pacific Research Laboratory Southwest

Preceptor: Donna Williams-Hill, Ph.D.

Scientific and Professional Background

Dr. Ashley Queen worked for the Department of Defense for seven years in areas of intelligence and acquisition. She concurrently earned a Bachelor of Science degree in Biology with a minor in Chemistry in 2009 from Coppin State University. She then attended graduate school at Howard University where she earned a Doctor of Philosophy in Microbiology in the spring of 2016. During her time as a student, she engaged in research at the Walter Reed Army Medical Research Institute in the division of malaria vaccine development. She also participated in research investigating the role of chronic infection on the activation of inflammatory cytokines in the prostate. Her dissertation work involved a genome wide association study where she identified an association of single nucleotide polymorphisms with the risk of developing breast cancer in a study population. Post-doctorate, she completed a program at a non-profit company where she conducted a study on biodefense/biosurveillance technologies and their capabilities to rapidly detect and screen for biothreat agents. She now joins the Microbiology Branch in the Office of Regulatory Affairs Pacific Regional Laboratory Southwest to engage in a high priority project aimed to validate a method that will improve the FDA's capability to detect and identify pathogens that may affect our nation's food supply.

Research Interests

Dr. Queen's area of expertise is in Microbiology. She has strong interests in public health and experience with work in mammalian and bacterial cell culture, bacteriophage isolation and characterization, health disparities studies, biodefense, bioinformatics, protein characterization and modeling, cancer genomics studies, and nucleic acid studies.

CFP Project Summary

Project Tile: *Validation of a universal broth for multi-pathogen enrichment from environmental swab samples*

FDA Regulatory Science Priority Area: Implement a New Prevention-Focused Food Safety System to Protect Public Health

Under the FDA priority area of implementing a new prevention-focused food safety system, the proposed research project is to identify and/or further develop a universal enrichment broth for the simultaneous enrichment of multiple bacterial pathogens. This includes Salmonella spp., pathogenic E. coli, Listeria monocytogenes, Staphylococcus aureus, and Shigella spp.; in environmental swabs. Per the AOAC guidelines, different surfaces will be tested for detection of low levels of pathogens which may include stainless steel, air filters, plastic, ceramic, rubber, concrete and cast iron using qPCR end points. The project will ultimately lead to a validated method for multiple pathogen analysis in environmental swabs for use in FDA field laboratories.

Tal Hila Salz, Ph.D.

CBER/OTAT/DCGT/Cell Therapies Branch (CTB)

Preceptor: Steven S. Oh, Ph.D.

Co-Preceptor: Mohammad Heidaran, Ph.D.

Scientific and Professional Background

2014-2016 Postdoctoral Fellow, Johns Hopkins University

2009-2014 Ph.D. in Biomedical Sciences, University of Florida, USA

2005-2008 B.Sc. in Biotechnology, Bar Ilan University, Israel

Research Interests

Tal has particular expertise in Genomics, Molecular & Cellular Biology, and Clinical & Translational Science. During her doctorate she discovered important epigenetic mechanisms in cancer and further developed novel epigenetic therapeutic strategies in oncology during her postdoc. Tal is interested in utilizing her interdisciplinary knowledge to advance innovative regulatory tools and policies that could enhance clinical development of safe and efficacious medical products. She has a particular interest in better understanding the existing manufacturing challenges that could potentially hinder successful commercialization of cell-based products and in developing well-defined strategies that could be useful for establishing product comparability.

CFP Project Summary

Project Title: *Enhancing Regulatory Science and Drug Development: Approaches To Advanced Manufacturing and Comparability of Cell-Based Therapeutics*

FDA Scientific Priority Area: Support New Approaches to Improve Product Manufacturing and Quality

Cell-based advanced therapeutic products are considered to be some of the most promising innovative medical products of the 21st century. Currently, most cellular products that are in late phases of clinical development are manufactured at a relatively small scale, often using conventional manufacturing schemes and tissue culture systems. Introduction of manufacturing changes including scale up and automation is an inevitable part of product improvement. For cell therapies, many changes in the manufacturing process could alter the relevant critical quality attributes of this class of products, thereby impacting the safety and efficacy of the drug product. For this reason, manufacturers are expected to demonstrate product comparability before and after manufacturing changes that could potentially have an adverse impact on product safety and efficacy. The primary objectives of this project are to: 1) identify major challenges in the large scale advanced manufacturing of cellular products, and 2) develop practical approaches and tools to facilitate a well-designed prospective comparability study. The results obtained from this study could be used as a framework and guidance for both the stakeholders during late clinical development and commercialization of cell-based products, and for the FDA in reviewing such products.

Zehra Tosun, Ph.D.

Multi-Center Fellowship in Regenerative Medicine

Center for Devices and Radiological Health (CDRH) / Center for Biologics Evaluation and Research (CBER)

Preceptors: Becky Robinson, Ph.D. (CBER) and Carolyn Yong, Ph.D. (CBER)

Scientific and Professional Background

2016	Product Development Manager, Amend Surgical
2012-2015	Senior Biomedical Engineer, NovaBone Products
2012	Ph.D., Biomedical Engineering, University of Florida, Gainesville, FL
2006	B.S., Chemical Engineering, Ankara University, Ankara, Turkey

Research Interests

Dr. Tosun's general research interests are cell-scaffold-based regenerative medicine products and regulatory issues surrounding this area due to their innovative nature and complexity. In her professional career, she focused on developing biomaterials for the repair and regeneration of hard and soft tissues. She managed product development projects from concept through prototyping to commercialization. Her graduate research focused on how biological materials interact with cellular systems to regenerate neo-organs. She characterized cellular, physical, and biomechanical changes within tissue-engineered products under a variety of conditions.

CFP Project Summary

Project Title: *Review Approaches for Iterative Development of Regenerative Medicine Products*

FDA Scientific Priority Area: Ensure FDA Readiness to Evaluate Innovate Emerging Technologies

Cell-scaffold-based regenerative medicine products offer promising innovative therapeutic strategies for the treatment of a broad range of clinical conditions. Such products consist of three-dimensional constructs in which viable cells are combined with matrices prepared from various materials to create tissue-engineered grafts for use in the repair, replacement, or regeneration of damaged tissues or organs. Due to their innovative and complex nature, regenerative medicine products require modification, or in some cases customization, throughout the course of their clinical development.

In a continuing effort to provide the earliest and broadest patient access to beneficial medical devices, the FDA has issued guidance intended to facilitate the clinical evaluation of medical devices in the US through new considerations for device development, which place an emphasis on both iterative medical device development and the implementation of timely device and clinical protocol modifications in early phases of clinical development. The guidance document recommends 'deconstructing' the medical device to develop a more thorough understanding of it through the identification of device-related attributes necessary to obtain the desired performance, as well as possible modes of failure (e.g., degradation rate, inflammatory reactions, immune response). The information gained from this deconstruction process should collectively better inform and streamline bench testing, animal testing, and regulatory review, as clinical development progresses. There is a question of whether the principles of iterative development through 'deconstruction" as outlined for medical devices in the CDRH guidance could be applied to development of the regenerative medicine products regulated by CBER/OTAT, and whether these principles have the potential to expedite patient access to these innovative medical products throughout the clinical development process—from early phase to pivotal studies.

Carolina Panico, M.D., Ph.D.

Center for Drug Research and Evaluation (CDER)

Office of New Drug/Immediate Office (OND/IO)

Preceptor: Christopher Leptak, M.D., Ph.D.

Scientific and Professional Background

2003: M.D., University of Naples, Italy

2008: Ph.D., University of Naples/Georgetown University

2009-2012: Georgetown University, Division of Nephrology, Post Doc

2013-2015: DC VAMC, Division of Endocrinology, Instructor Physiologist

2015-2016: George Washington University, Biochemistry, Senior Scientist

Research Interests

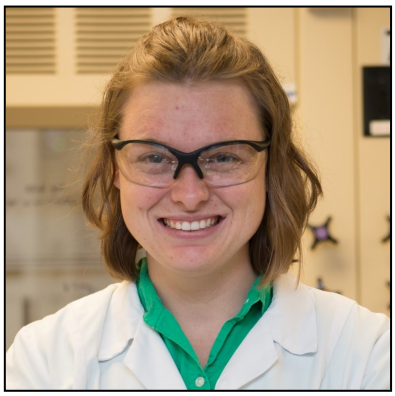
Dr. Panico's interests are: the involvement of the kidney and oxidative stress in the pathogenesis of essential hypertension, diabetes mellitus, and chronic kidney disease. Dr. Panico has participated in designing both clinical and translational studies to identify biomarkers for early detection of renal injury.

CFP Project Summary

Project title: "*Advancing the development of biomarkers to detect and monitor drug-induced kidney injury"*

FDA Scientific Priority Area the project falls under: *Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes.*

Current methods for detecting kidney toxicity are neither sensitive nor specific, and better tools are needed to monitor drug-induced kidney injury at all stages of the drug development process. To develop data to support the understanding and use of biomarkers for kidney safety assessment in early phases of clinical development, Dr. Panico will catalogue data and information submitted to FDA as part of IND and NDA submissions. In collaboration with team leaders in the Division of Cardiovascular and Renal Products, as well as external academic collaborators, she will determine how the data contained in these applications can be used to advance the understanding of renal biomarkers and expand this effort by identifying specific drug development needs and strategies that can be shared externally to assist stakeholder groups with interest in this area.



Desiree Van Haute, Ph.D.

Nanotechnology Core Facility

Arkansas Regional Lab

Office of Regulatory Affairs

Preceptor: Thilak Mudalige, Ph.D.

Scientific and Professional Background

2016 Ph.D., Biological Sciences

Irell and Manella Graduate School of Biological Sciences, Duarte, CA

The Synthesis and Biological Applications of Gold Nanoaggregates

2011 BS in Biomedical Engineering

Georgia Institute of Technology, Atlanta, GA

Research Interests

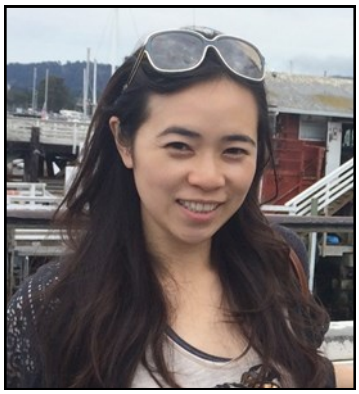
Desiree's primary research interest is the translation of nanomedicine from the laboratory to the clinic. Her previous research included the synthesis of controlled and homogeneous nanoparticle aggregates which were used to study how nanomaterials interacted in biological systems both in vitro and in vivo. While at the ORA Desiree is working to develop methods to characterize complex nanomedicines. In the future she hopes to leverage these experiences to help increase the number of quality nanomedicines that enter the clinic in order to improve patient quality of life and improve clinical outcomes.

CFP Project Summary

Project Title: *Physiochemical Characterization of Lipid-based Nano-Drug Complexes*

FDA Regulatory Science Priority Area*: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies*

The presence of nanomaterials in FDA-regulated products has increased over the last 20 years and is expected to continue to grow. Most characterization techniques require the analysis of a polydisperse solution of nanoparticles that contain variable concentrations of active pharmaceutical ingredients. The goal of this project is to develop techniques that combine size based separation with multiple characterization techniques in order to understand the relationship between nanoparticle size and the amount of active pharmaceutical ingredients in the nanoparticle. These methods could be extended to multiple types of nanoparticles and would allow for the comparison of generic and branded drugs.



I-Lin Wu, Ph.D.

Animal Drugs Research Center

Denver Laboratory

Office of Regulatory Affairs (ORA)

Preceptor: Sherri B. Turnipseed, Ph.D.

Scientific and Professional Background

2013-2016	Postdoctoral Research Fellow, National Cancer Institute, National Institutes of Health, Bethesda, MD
2013	Ph. D., Chemistry, Emory University, Atlanta, GA
2006-2007	Research Assistant, National Core Facilities for Proteomics and Glycomics, Tawian
2006	M.S., Biological Science, National Taiwan University, Taiwan
2004	B.S., Chemistry, National Taiwan University, Taiwan

Research Interests

Dr. I-Lin Wu's research background spans across bioanalytical chemistry, molecular and microbiology. She has extensive experience in protein purification, characterization, and the application of mass spectrometry. During her postdoctoral research training at NIH, she developed cancer therapeutics based on display platforms adapted from bacterial proteins. Her current interests align with the prevention and surveillance of antimicrobial resistance. Her work at FDA will be highlighted in the method development to monitor and detect chemical residues in the food with special focus of veterinary antibiotics.

CFP Project Summary

Project title: *Development and Application of High Resolution Mass Spectrometry (HRMS) Methods to Monitor Veterinary Drugs in Food*

FDA Scientific Priority Area: Implement a New Prevention-Based Food Safety System to Protect Public Health

Antimicrobials have been widely used in human and veterinary medicine for the prevention and treatment of infectious disease. Nowadays, the infections caused by antibiotic-resistant

Qianghua Xia, Ph.D.

National Center for Toxicological Research (NCTR)
Division of Bioinformatics and Biostatistics

Preceptor: Wenming Xiao, Ph.D.

Scientific and Professional Background

Education:

2011 Ph.D. Cancer Biology, The University of Texas Houston Health Science Center Graduate School of Biomedical Sciences and The University of Texas M.D. Anderson Cancer Center

2005 M.S. Genetics, University of Houston

1996 B.S. Environmental Biology & Ecology, Peking University

Experience:

2012-2016 Postdoctoral Fellow, 2013 The Children's Hospital of Philadelphia

2005-2011 Graduate Assistant, The University of Texas Houston Health Science Center Graduate School of Biomedical Sciences and The University of Texas M.D. Anderson Cancer Center

2001-2005 Graduate Assistant, University of Houston

Research Interests

Qianghua was trained as a cancer biologist at the University of Texas MD Anderson Cancer Center, where he studied pancreatic cancer progression. Following the completion of his Ph.D., he joined the Children's Hospital of Philadelphia (CHOP) to conduct post-GWAS functional studies in type2 diabetes.

CFP Project Summary

Project title: Evaluating and developing application of single cell sequencing in tumor early detection and treatment

FDA Scientific Priority Area: Stimulate Innovation in Clinical Trials and Personalized Medicine to Improve Product Development and Patient Outcomes

The presence of genetic differences among cancer cells within a tumor, called intratumor genetic heterogeneity, has long been observed in many cancer patients. Recent studies have documented that this genetic heterogeneity arises from a reiterative process of clonal expansion, genetic diversification and clonal selection within the adaptive landscapes of tissue micro-ecosystems. Therefore, the characteristics of tumor heterogeneity leads to a dramatic impact on therapeutic approaches and is believed to play a major role in initial therapeutic response. Personalized, selective strategies need to be designed to account for intratumor heterogeneity and better predict reoccurrence. In the project, the NGS results from single sequencing will be analyzed using multiple powerful bioinformatic tools. We aim to evaluate and develop application of single cell DNA and RNA sequencing for tumor early detection and treatment and thereby better predict treatment response and patient outcomes

Rachel Zamoiski, Ph.D.

Center for Tobacco Products

Preceptors: Nicolette Borek , Ph.D. (primary);
Bridget Ambrose, Ph.D., and Dana van Bemmel, Ph.D. (co-preceptors)

Scientific and Professional Background

BA, University of Pennsylvania, 2004

MPH, Johns Hopkins University, 2007

PhD, Johns Hopkins University, 2014

Postdoctoral Fellow, National Cancer Institute, 2014-2016

Research Interests

Rachel Zamoiski's training is in environmental epidemiology and cancer epidemiology. Her doctoral work focused on the interaction of metals and vitamin D, and her postdoctoral work was on ultraviolet radiation (sun exposure) and cancer risk. At FDA, Rachel is using her skills as an epidemiologist to research smoking behaviors and health, and is interested in the public health applications of epidemiological research.

CFP Project Summary

Project Title: *Adolescent use of tobacco and subsequent nicotine dependence*

FDA Scientific Priority Area: Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products

Rachel will be using data from the PATH (Population Assessment of Tobacco and Health) study to assess tobacco use and subsequent nicotine dependence in adolescents.

FDA Commissioner's Fellowship Program

2016 Preceptors

Nicolette Borek, Ph.D. (primary)

Bridget Ambrose, Ph.D., MPH (co-preceptor)

Dana van Bemmel, Ph.D., MPH (co-preceptor)

Office of Science/Center for Tobacco Products/FDA

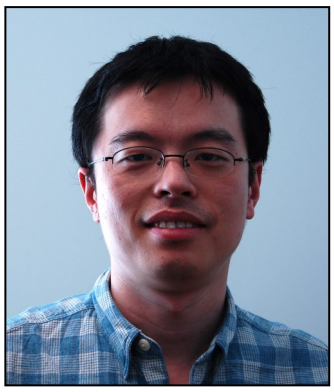
10903 New Hampshire Avenue, Silver Spring, MD

Research Interests:

Dr. Borek: Youth tobacco use, comorbid conditions, addiction, tobacco exposure and development

Dr. Ambrose: Understanding the appeal of tobacco to youth; harm reduction and population health

Dr. van Bemmel: Molecular epidemiology, biochemistry, biomarkers of tobacco exposure and bio-specimen collection, processing, and storage



Yi Chen, Ph.D.

Microbial Methods Development Branch

Division of Microbiology

Office of Regulatory Science

Center for Food Safety and Applied Nutrition

5100 Paint Branch Pkwy.

College Park, MD 20740

Background:

2003- 2007, Ph.D. The Pennsylvania State University

2008- Present, Food and Drug Administration

Research Interests:

Detection and enumeration of *L. monocytogenes* in food and environmental samples and whole genome sequencing analysis of *L. monocytogenes*

Sherry A. Ferguson, Ph.D.

Division of Neurotoxicology, HFT-132

National Center for Toxicological Research

3900 NCTR Road

Jefferson, AR 72079

Background:

Ph.D., Psychology, University of Wisconsin

22 years with the FDA

Research Interests:

Neurobehavioral toxicology, psychopharmacology, ethnicity differences in Alzheimer's Disease, sexually dimorphic behaviors

Mohammad A. Heidaran, Ph.D.

Biologist

Office of Cellular, Tissue and Gene Therapies

Center for Biologics Evaluation and Research

Silver Spring, MD

Background:

Ph.D., University of South Carolina

Postdoctoral Fellowship: National Cancer Institute

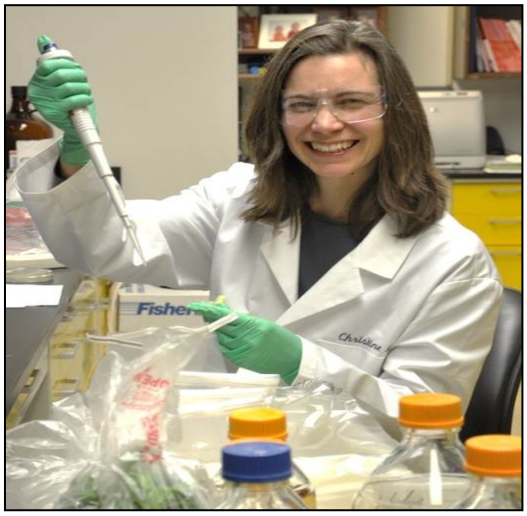
R&D Director Celgene and BD 2000-2010

FDA Experience – Since 2010

Research Interests:

Dr. Heidaran is currently a CMC Master Reviewer at CBER in the Office of Cellular, Tissue and Gene Therapies. His in-depth experience in evaluating Investigational New Drugs (INDs) and Biological License Applications (BLAs) comes from both product and facility Current Good Manufacturing Practices (CGMPs) compliance review. He has extensive regulatory knowledge of CGMPs, and pre and post license inspection of CGMP manufacturing facilities for biologics.

Dr. Heidaran has a multidisciplinary academic and industrial background in applied cell biology and innovative cell therapy and tissue engineering product development. He also has hands-on industrial experience in manufacturing of cell therapy products. His extensive product development, manufacturing experiences, and comprehensive experiences with manufacturing devices allow him to provide a unique insight and perspective in regulatory review and policy making activities. His regulatory work and outreach activities emphasize the importance of defining the critical quality attributes and critical process parameters for large scale manufacturing of the cellular products. His long lasting scientific interest is to understand the molecular control mechanisms that regulate growth and differentiation of stem cells expanded in the three-dimensional microenvironments. He is also founder of prestigious Gordon Research Conference in “Signal Transduction by Engineered ECMs”.



Christine Karbiwnyk, Ph.D.

Winchester Engineering and Analytical Center, ORA

Winchester MA 01890

Background:

B.S. Chemistry, University of New Haven

B.S. Forensic Science, University of New Haven

Ph.D. Analytical Chemistry, University of Colorado-Boulder

FDA experience 14 years

Research Interests:

Applying new technologies to chemistry and microbiology regulatory analysis.

Christopher Leptak, M.D., Ph.D.

OND Biomarker and Companion Diagnostic Lead,

Co-Director Biomarker Qualification Program

Office of New Drugs (OND) /Immediate Office (IO)

CDER/FDA

10903 New Hampshire Avenue

White Oak Building 22, Silver Spring, MD 20993-0002

Background:

1999: M.D., Ph.D., University of California, San Francisco
2003: Residency in Emergency Medicine, Harvard program at Brigham and Mass General Hospitals
2007: Joined FDA as a primary clinical reviewer in GI division
2010: Joined the OND IO Guidance and Policy Team

Research Interests:

Regulatory science, drug development tools, biomarker development, targeted therapies, companion diagnostics, innovative clinical trial designs, novel technologies in drug development

Ke Liu, M.D., Ph.D.

Chief, Oncology Branch

Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT)

Office of Cellular, Tissue, and Gene Therapies (OCTGT)

Center for Biologics Evaluation and Research (CBER

Research Interests:

Dr. Liu is Chief of the Oncology Branch of CBER/OCTGT and would serve as Preceptor for this fellowship. As Branch Chief, he is responsible for overseeing the clinical review, regulation, and policy development for cell therapy and gene therapy intended for the diagnosis or treatment of cancer and regulated by CBER/OCTGT. Prior to serving as chief of the oncology branch, .r Liu worked in the Center for Drug Evaluation and Research, as a lead medical officer in the Office Oncologic Drug Products. Dr. Liu is a member of the Society for the Immunotherapy of Cancer, and was the organizer of the Global Regulatory Summit at the Society's last meeting. He has been an invited speaker at meetings of the Drug Information Agency, American Scotty of clinical Oncology and American Association for Cancer Research. Dr. Liu has received numerous awards while at FDA, and has served as a preceptor for the FDA-NCI Interagency Oncology Task Force. Dr. Liu is an attending physician at the Washington Veteran's Administration Medical Center

Michelle M. Moore, Ph.D.

Applied Technology Center, Pacific NW Laboratory
ORA

22201 23rd Drive SE, Bothell, WA 98021

Background:

-B.S. Biology

-M.S. Fisheries Sciences

-Ph.D. Veterinary Sciences

-NRC Post-doctoral and Senior Research Fellow 4 years (NMFS)

-ORISE Post-doctoral Fellow 1 year (NMFS)

More information on Linked In and ResearchGate

Research Interests:

I work on the development and validation of molecular identification methods for bacterial foodborne pathogens and seafood (fish) species. Currently I am involved in development, evaluation and/or validation of methods utilizing liquid array (Bio-Plex) for Salmonella molecular serotyping; DNA sequencing, including "DNA Barcoding" to identify fish species and bacteria, and whole genome sequencing (MiSeq). My primary foodborne pathogen of interest is Salmonella.

B

Thilak K. Mudalige, Ph.D.

Nanotechnology Core Facility, Arkansas Regional Laboratory (ARL) (ORA)

Jefferson, AR

Background:

Postdoctoral Research Associate, Brookhaven National Laboratory, NY

Ph. D. - Chemistry, Western Michigan University

B. S. - Chemistry, University of Colombo, Sri Lanka

FDA Experience - 6 Years

Research Interests:

- My research is at the interface of materials chemistry, analytical chemistry, and nanotechnology.
- Development of hyphenated size-based separation techniques using asymmetric flow field flow fractionation, inductively coupled plasma/mass spectrometry (ICP/MS), light scattering detectors, and conductivity detector.
- Development of hyphenated size-based separation techniques using centrifugal field flow fractionation, inductively coupled plasma/mass spectrometry (ICP/MS), light scattering detectors, and conductivity detector.
- Development of hyphenated size-based separation and speciation techniques using capillary electrophoresis, and inductively coupled plasma/mass spectrometry (ICP/MS)
- Application of x-ray fluorescence (XRF) spectroscopy as a screening tool for nanoscale materials in FDA regulated products.
- Development of single particle mode ICP/MS for the characterization of nanoparticles in FDA regulated products.

Steven S. Oh, Ph.D.

Chief, Cell Therapies Branch

Office of Cellular, Tissue and Gene Therapies

Center for Biologics Evaluation and Research

Silver Spring, MD

Background:

Ph.D., University of Michigan

Postdoctoral Fellowship: Johns Hopkins University School of Medicine & Massachusetts Institute of Technology

Faculty, Tufts University School of Medicine

FDA Experience – Since 2007

Research Interests:

Dr. Oh is Chief of Cell Therapies Branch (CTB) which regulates cell-based therapeutic products, tissue-engineered products, combination products, and point-of-care devices having therapeutic or regenerative indications. Dr. Oh provides leadership in reaching various regulatory decisions on medical products submitted to Office of Cellular, Tissue and Gene Therapies (OCTGT) in Center for Biologics Evaluation and Research (CBER) for marketing, clinical investigation, or product classification in the U.S. He is actively involved in the development of regulatory policies for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) and cell-based combination products. He interacts closely with Center for Devices and Radiological Health (CDRH) and Center for Drug Evaluation and Research (CDER) in FDA and with other government agencies on cross-cutting scientific and regulatory issues and policies. Dr. Oh participate in international standards activities in the manufacture and testing of cellular products and tissue -engineered medical products. In addition, Dr. Oh is engaged in various efforts promoting global regulatory convergence in cell-based therapeutic products.

Barbara L. Parsons, Ph.D.

Division of Genetic and Molecular Toxicology/NCTR

3900 NCTR Rd., Jefferson, AR

Background:

B.S., SUNY Binghamton, 1980

Ph.D., Duke University, 1988

FDA employment, 1998-present

Research Interests:

My research interests are in developing cancer driver mutations as quantitative biomarkers of cancer risk and investigating their utility in: 1) preclinical safety assessment, 2) improving the scientific basis for rodent to human extrapolation, and 3) developing knowledge that will speed the availability of efficacious personalized cancer treatments.

Anil K. Patri, Ph.D.

NCTR-ORA Nanotechnology Core Facility

Office of Scientific Coordination

National Center for Toxicological Research (NCTR)

FDA Jefferson Laboratories Campus

Jefferson, Arkansas 72079

Background:

Ph.D.

5 months at FDA (August 2014-present)

Over 20 years experience in Nanotechnology with 10 years at the Frederick National Laboratory for Cancer

Research on preclinical assessment of nanomedicines.

Research Interests:

All aspects of nanotechnology regulatory research in medical products from synthesis of nanomaterial based drugs, imaging agents and devices, material characterization, in vitro biocompatibility and in vivo safety and efficacy assessment.

Becky Robinson, Ph.D.

Team Leader & Biomedical Engineer

Pharmacology/Toxicology Branch (PTB)

Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT)

Office of Cellular, Tissue, and Gene Therapies (OCTGT)

Center for Biologics Evaluation and Research (CBER)

Background:

PhD, Biomedical Engineering, Yale University

MS, Neuroengineering, Yale University

BS, Biomedical Engineering, Columbia University

At the FDA since 2010

Regulatory Interests:

The Cell Therapies Branch (CTB) is responsible for the regulatory review of the chemistry, manufacturing, and controls (CMC) information submitted to CBER/OCTGT to support the safe use of investigational cellular therapies in human clinical trials. As a Team Leader in CTB, Carolyn Yong conducts scientific regulatory review while providing oversight of DCGT programs related to regenerative medicine applications and combination products containing a biological product in combination with a device and/or drug. She is also engaged in both FDA and standards organization activities related to tissue engineered medical products. Prior to joining CBER/OCTGT in October of 2014, Carolyn was a Lead Scientific Reviewer in the Plastic and Reconstructive Surgery Devices Branches (PRSB) in the Division of Surgical Devices (DSD) in the Office of Device Evaluation (ODE) in the Center for Devices and Radiological Health (CDRH). Carolyn was previously a Commissioner's Fellow (Class of 2012), where she conducted regulatory review work in both CBER/OCTGT and CDRH/ODE. Since joining OCTGT, her inter-Center experiences have afforded her the opportunity to serve as a liaison between CBER and CDRH for biologic-device combination products, as well as provide mentorship and contribute to training programs related to medical device review for CBER staff.

Additionally, the Pharmacology/Toxicology Branch (PTB) is responsible for the regulatory review of all preclinical studies submitted to CBER/OCTGT to support the safe use of an investigational cell therapy, gene therapy, or tissue-engineered product in human clinical trials. As a Team Leader in the PTB, Becky Robinson provides scientific and regulatory oversight of regulatory submissions generated by a team of experienced Pharmacology/Toxicology reviewers. Prior to joining CBER/OCTGT in January of 2015, Becky was a Lead Scientific Reviewer in the Obstetrics and Gynecology Devices Branch (OGDB) in the Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD) in the Office of Device Evaluation (ODE) in the Center for Devices and Radiological Health (CDRH). During this time Becky served as the DRGUD Early Feasibility Studies (EFS) Program representative and represented DRGUD and ODE on various CDRH working groups. While at the FDA, Becky has been a lead contributor to multiple FDA guidance documents and the reclassification effort for surgical mesh devices placed transvaginally for repair of pelvic organ prolapse. Becky was previously a Commissioner's Fellow (Class of 2010), where she conducted regulatory review work in CBER/OCTGT and CDRH/ODE, as well as designed a database cataloging all surgical mesh device 510(k) Premarket Notifications. Since joining OCTGT, these inter-Center experiences have afforded her the opportunity to consult on biologic-device combination products, as well as provide mentorship and training related to medical device review for OCTGT staff.

Nakissa Sadrieh, Ph.D.

Director, Cosmetics Division

Office of Cosmetics and Colors

FDA Center for Food Safety and Applied Nutrition

College Park, MD

Education:

Ph.D. Toxicology Rutgers University 1993

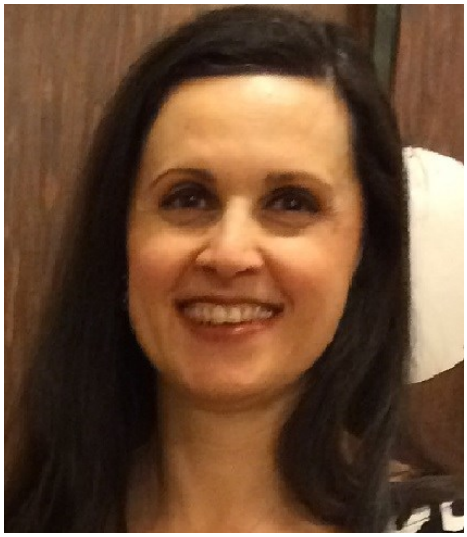
B.S. Biology, Montclair State University 1987

Experience:

2013-present: CFSAN/FDA; Director, Cosmetics Division

1996-2013: CDER/FDA; Associate Director for Research Policy and Implementation

1993-1996: NCI/NIH; IRTA fellow



Azadeh Shoaibi, Ph.D., MHS, MS

CBER/OBE/IO

10903 New Hampshire Ave. WO-71

Silver Spring, MD 20993

Background:

Education:

Doctor of Philosophy in Epidemiology from University of Maryland Baltimore

Master of Science in Epidemiology from University of California Los Angeles School of Public Health

Master of Health Science in Molecular Microbiology and Immunology from Johns Hopkins School of Public Health

FDA employment:

CBER/Office of Biostatistics and Epidemiology/Immediate Office of Director: Nov. 2015- present

CDER/Office of Medical Policy/Office of Medical Policy Initiatives: Sep. 2010-Nov. 2015

CDRH/Office of Surveillance and Biometrics/Division of Epidemiology: Apr. 2004-Sep. 2010

Research Interests:

- Pharmacoepidemiology
- Epidemiology of medical devices

Rob Sokolic, M.D.

Medical officer, Oncology Branch

Division of Clinical Evaluation and Pharmacology/ Toxicology (DCEPT)

Office of Cellular, Tissue, and Gene Therapies (OCTGT)

Background:

BA and M.D., Brown University

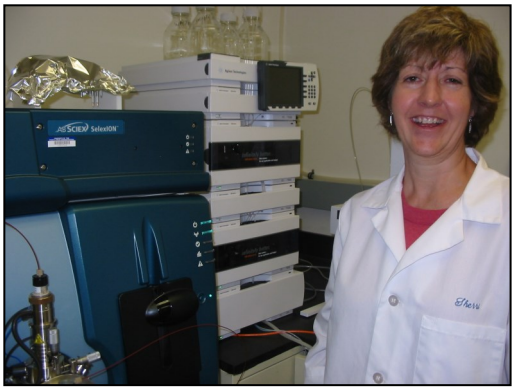
Resident in Internal Medicine Hospital of hte University of Pennsylvania

Fellow in Oncology and Hematology, Memorial Sloan-Kettering Cancer Center and the National Cancer institute

Staff clinician and attending physician, National Human Genome Research Institute

Research Interests:

Dr. Sokolic is a medical officer in the oncology branch. He came to FDA in 2014, after a decade as a fellow, staff clinician and principal investigator at the National Institutes of Health. His clinical background is in cell and gene therapy for hematologic malignancy and primary immunodeficiency disorders. Dr. Sokolic's research interests include the treatment of cancer and primary immunodeficiencies, the natural history of rare diseases and methodological issues in their study, and the assessment of quality of life and patient preferences as they inform treatment choices in primary immunodeficiencies and rare diseases. Dr. Sokolic has contributed to more than fifty clinical papers, review articles and scientific abstracts. He has been an invited participant at meetings of the Primary Immunodeficiency Treatment consortium, the Clinical Immunology Society summer school on immune deficiency and the first international meeting on Wiskott-Aldrich syndrome and X-linked lymphoproliferative disease. Dr. Sokolic serves as the OCTGT representative to the FDA Rare Diseases Council. Dr. Sokolic volunteers in the primary immunodeficiency clinic at Johns Hopkins Hospital.



Sherri Turnipseed, Ph.D.

Animal Drugs Research Center

Denver Laboratory

FDA, Office of Regulatory Affairs (ORA)

Denver Federal Center, Bldg 20

Denver, CO 80225

Background:

Colorado State University, B.S. 1984

Major: Chemistry. Minor: Biochemistry

University of Colorado, Ph.D., May 1990

Major: Analytical Chemistry

23 years FDA employment as Research Chemist with Animal Drugs Research Center

Research Interests:

Developing analytical methods for the monitoring of veterinary drug residues in food products using high resolution mass spectrometry, expanding the scope of chemical contaminant analyses, and exploring emerging technologies to increase the efficiency and effectiveness of regulatory analytical methods.

Wenming Xiao, Ph.D.

Division of Bioinformatics and Biostatistics

NCTR/FDA

Background:

MS in Statistics and Computer Science

Ph.D in Genetics and Molecular Biology

Years with FDA: 2

Years with NCI/NIH: 10

Years with Industry: 6

Research Interests:

My research interest is to develop and apply integrated bioinformatics methodologies for "omic" data, particularly those generated from the next generation of sequencing and microarray platforms, to identify biomarkers for tumor early detection and treatment prognosis, and to establish quality metrics and bioinformatics solutions for personal genome assembly for clinical applications. Ultimately, molecular data and knowledge accumulated from this line of research would help to develop guidance and protocol for biomarker development and clinical trial that could lead an enhanced approach towards precision and personalized medicine. My research mainly focuses on two areas:

1. Personal genome assembly and quality metrics

Precision medicine is based on interrogation of genetic alteration in one individual, which requires precise and complete characterization of personal genome. Whole genome sequencing has been becoming cheaper and affordable and the challenge of routinely applying it in the precision medicine era largely rests on bioinformatics solution, particularly for personal genome assembly. My study is to establish the best practice of personal genome assembly and quality matrices and to provide guidance for usage of personal genome in clinical application by investigating the impact of various the next-generation sequencing (NGS) parameters, such as coverage, read length, and methods on assembly quality.

2. Circulating cell-free DNA detection

Circulating cell-free DNA (ccfDNA) has been considered as "liquid biopsy" that contains genetic information for diagnosis purpose. They are small fragmented DNA released from normal or diseased cells due to necrosis or apoptosis process. Recently, people start to use ccfDNA to categorize tumors for clinical decision because of its nature of rapid, cost-effective and non-invasive. More importantly, ccfDNA would have better representation of tumor heterogeneity than single tissue biopsies and thus provide better guidance for treatment decisions. However, since the amount of ccfDNA in circulating DNA could be as little as 0.01%, standard procedures for preanalytical and analytical processes need to be established before it could be routinely used in clinical settings. Through prospective studies, we will interrogate genetic background of circulating DNA in normal individual or individual with a known disease state or physiologic state and ccfDNA from cancer patients undergoing therapeutic treatments. While we will gain knowledge for genomic background metrics, sensitivity and specificity of ccfDNA detection; we will also develop bioinformatics tools and analytical workflow for ccfDNA detection with NGS technology.

Carolyn Yong, Ph.D.

Team Leader, Device and Combination Products

Cell Therapies Branch (CTB)

Division of Cellular and Gene Therapies (DCGT)

Office of Cellular, Tissue, and Gene Therapies (OCTGT)

Center for Biologics Evaluation and Research (CBER)

Background:

BSE Biomedical & Chemical Engineering, Johns Hopkins University

MSE Chemical Engineering, Johns Hopkins University

Ph.D. Bioengineering and Biotechnology, École Polytechnique Fédérale de Lausanne, Switzerland

At the FDA since 2012

Regulatory Interests:

The Cell Therapies Branch (CTB) is responsible for the regulatory review of the chemistry, manufacturing, and controls (CMC) information submitted to CBER/OCTGT to support the safe use of investigational cellular therapies in human clinical trials. As a Team Leader in CTB, Carolyn Yong conducts scientific regulatory review while providing oversight of DCGT programs related to regenerative medicine applications and combination products containing a biological product in combination with a device and/or drug. She is also engaged in both FDA and standards organization activities related to tissue engineered medical products. Prior to joining CBER/OCTGT in October of 2014, Carolyn was a Lead Scientific Reviewer in the Plastic and Reconstructive Surgery Devices Branches (PRSB) in the Division of Surgical Devices (DSD) in the Office of Device Evaluation (ODE) in the Center for Devices and Radiological Health (CDRH). Carolyn was previously a Commissioner's Fellow (Class of 2012), where she conducted regulatory review work in both CBER/OCTGT and CDRH/ODE. Since joining OCTGT, her inter-Center experiences have afforded her the opportunity to serve as a liaison between CBER and CDRH for biologic-device combination products, as well as provide mentorship and contribute to training programs related to medical device review for CBER staff.

Additionally, the Pharmacology/Toxicology Branch (PTB) is responsible for the regulatory review of all preclinical studies submitted to CBER/OCTGT to support the safe use of an investigational cell therapy, gene therapy, or tissue-engineered product in human clinical trials. As a Team Leader in the PTB, Becky Robinson provides scientific and regulatory oversight of regulatory submissions generated by a team of experienced Pharmacology/Toxicology reviewers. Prior to joining CBER/OCTGT in January of 2015, Becky was a Lead Scientific Reviewer in the Obstetrics and Gynecology Devices Branch (OGDB) in the Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD) in the CDRH's ODE. During this time, Becky served as the DRGUD Early Feasibility Studies (EFS) Program representative and represented DRGUD and ODE on various CDRH working groups. While at the FDA, Becky has been a lead contributor to multiple FDA guidance documents and the reclassification effort for surgical mesh devices placed transvaginally for repair of pelvic organ prolapse. Becky was previously a Commissioner's Fellow (Class of 2010), where she conducted regulatory review work in CBER/OCTGT and CDRH/ODE, as well as designed a database cataloging all surgical mesh device 510(k) Premarket Notifications. Since joining OCTGT, these inter-Center experiences have afforded her the opportunity to consult on biologic-device combination products, as well as provide mentorship and training related to medical device review for OCTGT staff.