FDA Commissioner's Fellowship Program

Class of 2013

FDA Commissioner's Fellowship Program

2013 Fellows

FDA Commissioner's Fellowship Program

2013 Preceptors

FDA Commissioner's Fellowship Program

2013 Preceptors and Fellows Projects listed by Regulatory Science Priority Area

Modernize Toxicology to Enhance Product Safety – 3

- Jeffrey Fisher (Fellow: Andrew Fu)
- Sangeeta Khare (Fellow: Aschalew Bekele)
- Igor Pogribny and Fredrick Beland (Fellow: April Marrone)

Support New Approaches to Improve Product Manufacturing and Quality - 1

- Stephen Torosian (Fellow: Aaron Bandremer)

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies - 2

Multi-Center Fellowship in Regenerative Medicine (CBER and CDRH)

- Mercedes Serabian, Elias Mallis, and Aric Kaiser (Fellows: Sarah Brittain and Iwen Wu)

Harness Diverse Data through Information Sciences to Improve Health Outcomes - 1

- Elizabeth Sutkowski (Fellow: Pin Zhang)

Implement a New Prevention-Focused Food Safety System to Protect Public Health - 3

- Narjol Gonzalez-Escalona (Fellow: Krishna Hamal)
- Irshad Sulaiman (Fellow: Katie Swensen-Segars)
- Cong Wei (Fellow: James (Paul) Kirwan)

Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security - 3

- Dionna Green (Fellow: Rita Humeniuk)
- Sanjai Kumar (Fellow: Bryan Grabias)
- Suzanne Schwartz (Fellow: Aftin Ross)

FDA Commissioner's Fellowship Program

2013 Preceptors and Fellows by Center

CBER	
Preceptor	**Fellow**
Mercedes Serabian	Iwen Wu
Elizabeth Sutkowski	Pin Zhang
CDRH	
Preceptor	**Fellow**
Elias Mallis, Aric Kaiser, and Mercedes Serabian (CBER)	Sarah Brittain
CFSAN	
Preceptor	**Fellow**
Narjol Gonzalez-Escalona	Krishna Hamal
MCMi-CBER	
Preceptor	**Fellow**
Sanjai Kumar	Bryan Grabias
MCMi-CDER	
Preceptor	**Fellow**
Dionna Green	Rita Humeniuk
MCMi-CDRH	
Preceptor	**Fellow**
Suzanne Schwartz	Aftin Ross
NCTR	
Preceptor	**Fellow**
Fredrick Beland and Igor Porgribny	April Marrone
Sangeeta Khare	Aschalew Bekele
Jeffrey Fisher	Andrew Fu
ORA	
Preceoptor	**Fellow**
Irshad Sulaiman	Katie Swensen-Segars
Stephen Torosian	Aaron Bandremer
Cong Wei	James (Paul) Kirwan

FDA Commissioner's Fellowship Program

2013 Fellows

Aaron Bandremer, M.S.

Office of Regulatory Affairs (ORA)

Preceptor: Stephen Torosian, Ph.D.

Scientific and Professional Background

2010-2013	Senior Engineer, Bioprocess Development, OPK Biotech, LLC.
2009-2010	Purification Scientist, Shire Pharmaceuticals
2009	M.S., Biomedical Engineering and Biotechnology, University of Massachusetts Intercampus Program
2004-2008	Associate Scientist, Protein and Cell Sciences, EMD Serono
1999-2004	Development Engineer, Biopure Corporation
1997-1999	Research Associate, Regeneron Pharmaceuticals
1996	B.S., Chemical Engineering, Rensselaer Polytechnic Institute

Research Interests

Aaron's research interests broadly lie in the fields of biotechnology, nanotechnology and their interface. He has developed both cGMP and pilot processes for the production of hemoglobin based oxygen carriers and protein therapeutics. Aaron has investigated techniques for the fabrication of novel optical metamaterials based on the chemical and biological self-assembly of nanoparticles. These techniques have also been employed to research his interest in biosensors for the rapid detection of analytes.

Commissioner's Fellowship Project Overview
Development of a field capable device designed to reduce environmental sampling analysis times from 5 days to hours

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

The goal of this research project is the development of a portable biosensor platform for environmental and later, food analysis. Novel biosensor concepts incorporating conductive electropsun membranes will be employed to reduce the following: 1) sample processing time, 2) weight of detection platforms and 3) the amount of reagents required to run samples. The high surface area geometry of electrospun membranes allows for an optimum concentration of antibody (or other binding elements) attachment thereby, increasing the sensitivity of the detection. Ongoing studies will optimize membrane characteristics, conductive polymer deposition, and the functionalization of antibody to membrane. An electrochemical cell will be designed and constructed in order to convert the antibody-antigen interaction into a measurable signal that can be used for ongoing and instantaneous detection.

Aschalew Bekele, Ph.D

National Center for Toxicological Research (NCTR)
Division of Microbiology

Preceptor: Sangeeta Khare, Ph.D.

Scientific and Professional Background

2012-2013	Postdoctoral Associate, University of Minnesota
2009-2012	Ph.D. Microbiology, Hokkaido University, Japan
2007-2009	MSc, Microbiology, Hokkaido University, Japan
2005-2006	Pre-doctoral Fellow, Swiss Federal Institute of Technology, Switzerland
2001-2005	Vaccine Research and Production Officer, National Veterinary Institute, Ethiopia.
1998-2000	Research Assistant, International Livestock Research Institute
1992-1998	DVM Veterinary Medicine, Addis Ababa University, Debre Zeit, Ethiopia

Research Interests

My research focus is related to understanding and manipulating the gut virobiota towards maintaining gut homeostasis and health. The gastro intestinal tract is home for billions of commensal microbes which play significant roles in host nutrition, metabolism, immune development, and occurrence of range of diseases from obesity, diabetes, allergies and inflammatory bowel diseases to elevated cancer risk. Therefore maintaining a normally functioning microbiota is crucial to the overall human health. Presence of viruses in the gut may play a major role in the overall balance of gut microbiota population. During my graduate and postdoctoral years, I have worked in projects that aimed at analyzing how the microbiota responds to diet induced changes as well as on molecular typing of specific bacterial enteric pathogens. As a FDA fellow, I am keen to learn the safety assessment of food/feed additives and contaminants, with particular focus on health risk associated with the exposure of the gastrointestinal tract and the virobiota to nanoparticles.

Commissioner's Fellowship Project Overview
Evaluation of effects of nanoparticles on enteric microbiota and virobiota

FDA Regulatory Science Priority Area: Modernize Toxicology to Enhance Product Safety.

The resident gut microbiota is constantly bombarded by both intentionally and accidentally ingested substances that disturb its function. Recently, the use of nanoparticles (NPs) in consumer products has been increasing. There are now more than 1600 products on the market that incorporated nanoscale materials in food, beverages, food packages, children items, cosmetics and several household items. This widespread use of NPs will ultimately result in increased human exposure and the GIT is the main route of entry to the NPs. Although there is accumulated evidence on the antimicrobial properties of NPs, we have yet to understand the collateral side effects of ingested NPs on microbes. In this project we will explore how the commonly used NPs in food and feed affect the virobiota so as to estimate the potential risk of exposure of NPs to host gut health and disease.

Sarah Brittain, M.S.

Multi-Center Fellowship in Regenerative Medicine

Center for Devices and Radiological Health (CDRH)

Center for Biologics Evaluation and Research (CBER)

Preceptors: Aric Kaiser, M.S. (CDRH), Elias Mallis (CDRH), Mercedes Serabian, M.S., DABT (CBER), and Pakwai Au, Ph.D., DABT (CBER)

Scientific and Professional Background

2013 M.S. Biomedical Engineering
University of Connecticut

2011 B.S. Biomedical Engineering
University of Connecticut

Research Interests

Sarah's main research interests are in biomaterials for regenerative medicine. Her graduate research focused on the development and characterization of an enzymatically cross-linked glycol-chitosan hydrogel as a delivery vehicle to support bone and cartilage regeneration. This injectable hydrogel was ideal for minimally invasive applications and provided a mild environment for encapsulated cells, drugs or other biological factors to be delivered locally to the injured site and promote tissue regeneration.

Commissioner's Fellowship Project Overview
Evaluation and assessment of FDA review of bone void filler devices with increased regenerative properties without the use of biological factors

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

Advances in biomaterials research for regenerative medicine have allowed for a greater understanding of the processing techniques that may be used to alter the physical structure of materials and the biological responses elicited after implantation. In orthopaedics, this is becoming increasingly apparent in the bone void filler products which do not contain additional biological factors such as recombinant growth factors or synthetic peptides (recognized osteogenic components), yet claim to have increased bone regeneration properties. This has created the challenge of determining how to properly regulate these new devices in the most effective manner, *e.g.*, alternate regulatory pathways, to ensure their unique properties are appropriately evaluated and accounted for. The overall goals of this project are to provide greater understanding into the biological regenerative response to calcium salt bone void filler material properties, as well as recommending a regulatory review pathway for these types of devices.

Andrew Fu, Ph.D.

National Center of Toxicological Research (NCTR)
Division of Biochemical Toxicology

Preceptor: Jeffrey Fisher, Ph.D.

Scientific and Professional Background

2007 B.S. Biomedical Engineering, Johns Hopkins University, Baltimore, MD

2013 Ph.D. Biomedical Engineering, Case Western Reserve University, Cleveland, OH

2013 Fellow & Consultant, The Entrepreneurs EDGE, Cleveland, OH

Research Interests

Trained as a biomedical engineering, Andrew is especially interested in inter- and multi-disciplinary approaches to solving biological problems. His previous research focused on engineering reloadable drug delivery implant for glioblastoma treatment and mechanistic modeling of tissue engineering and drug delivery systems. He hopes to apply his skills and expertise to facilitate FDA's efforts in human health risk assessment and medical device evaluations.

Commissioner's Fellowship Project Overview

Physiologically based pharmacokinetic modeling: Prediction and evaluation of tissue dosimetry of cobalt ions and particles released from metal-on-metal bearings of hip replacements

FDA Regulatory Science Priority Area: Modernize Toxicology to Enhance Product Safety

Despite rising concerns for adverse local responses and potential systemic toxicity of cobalt (Co) exposure, investigations on the biokinetics of prosthesis-derived Co debris remain scarce. Large-scale clinical studies of metal debris dynamics in humans would undoubtedly be costly and impractical. Alternatively, we propose to develop a physiologically based pharmacokinetic (PBPK) model to predict tissue dosimetry of Co released from MoM implants based on available human and animal data. Our proposed PBPK model would facilitate FDA's evaluation of the safety of MoM implants and of the risks of long-term exposure to postoperative cobalt. Furthermore, it is our hope that, the model, a first of its kind, would serve as a basis for developing future models to predict metal debris released from a variety of medical implants.

Bryan Grabias, Ph.D.

Center for Biologic Evaluation and Research (CBER)

Preceptor: Sanjai Kumar, Ph.D.

Scientific and Professional Background

2012-2013	Postdoctoral Researcher, Chemical & Biomolecular Engineering
	Johns Hopkins University
2012	Ph.D., Chemical & Biomolecular Engineering
	Johns Hopkins University
2006	B.S., Chemical Engineering
	Columbia University

Research Interests

Bryan's research interests have focused on exploring the molecular and cellular mechanisms of disease. In his graduate work, he studied the progression of renal fibrosis by examining the effects of supraphysiological fluid shear stress on renal epithelial cell function, differentiation, and matrix synthesis. In particular, Bryan discovered that distinct oscillatory activation patterns of fibrotic signaling cascades govern overall phenotypic outcomes. His postdoctoral work identified novel signaling pathways that contribute to pancreatic cancer cell migration and invasion downstream of the selectin ligand and stem cell marker PODXL. As an engineer, Bryan is excited to be at the FDA because his foremost concern is the translation of basic research discoveries into safe and effective diagnostic/therapeutic applications.

Commissioner's Fellowship Project Overview
Design of a Sensitive & Specific Multiplex Platform for Pathogen Detection

FDA Regulatory Science Priority Area: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security

Highly sensitive and specific detection of infectious pathogens is required for effective diagnosis and surveillance of disease transmission. This is particularly true for the protozoan malaria parasite *Plasmodium Falciparum,* as declines in global levels of transmission necessitate the scrutiny of lower parasite densities. During the Commissioner's Fellowship program, Bryan's aim is to design and validate a novel, cutting-edge antigen detection platform that improves upon the current gold-standard ELISA assay. In particular, a number of design constraints will be considered. For everyday operation in the field, experimental requirements and protocols must be limited; however, an ideal assay should simultaneously allow scalability for high-throughput screening of the blood supply. Furthermore, an assay amenable to multiplexing would also allow for rapid detection and speciation of multiple emerging pathogens such as Chikungunya virus or bio-terror agents (e.g., Bacillus anthracis, Ebola virus etc.). An accurate and efficient diagnostic test is thus not only a critical bulwark of global health but also key to safeguarding national security.

Krishna Hamal, Ph.D.

Center for Food Safety and Applied Nutrition (CFSAN)

Preceptor: Narjol Gonzalez-Escalona, Ph.D.

Scientific and Professional Background

2012-2013	Visiting Scientist, Exotic and Emerging Avian Viral Diseases Research Unit, Southeast Poultry Research Laboratory, USDA/ARS, Athens, GA
2012-2012	Assistant Research Scientist (≈Assistant Research Professor), Department of Infectious Disease, College of Veterinary Medicine, University of Georgia, Athens, GA
2008-2012	Program Associate I/Postdoctoral Fellow, The Center of Excellence for Poultry Science, University of Arkansas, Fayetteville, AR
2008	Ph.D. in Poultry Science, University of Arkansas, Fayetteville, AR
1995-2000	Bachelor of Veterinary Sciences and Animal Husbandry (B.V.Sc. & A.H., DVM), Acharya N.G. Ranga Agricultural University, Hyderabad, India

Research Interests

Dr. Hamal's research interests lies in the fields of food borne pathogens, zoonotic and emerging diseases, biothreat agents, food safety, and public health. His research plan at FDA is to apply his knowledge and experience in microbiology, molecular biology, and genomics for the development of methods for rapid and accurate detection of foodborne pathogens.

Commissioner's Fellowship Project Overview

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

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

A contamination by *Salmonella* Senftenberg in frozen mussels was detected in 1998 during a routine analytical surveillance. From June 1998 to December 2001, a total of 3,410 samples of steamed frozen mussels and items related to their manufacture were analyzed for the presence of *Salmonella*. *Salmonella* Senftenberg was isolated in 573 (16.8%) samples, and no other serovar was detected. A total of 60 *Salmonella* serovar Senftenberg isolates, originating from surveillance activities in marine environments, was subjected to molecular characterization by pulsed-field gel electrophoresis (PFGE). PFGE analysis of the marine isolates allowed the differentiation of three main PFGE types, which contained the majority of the isolates, each type showing a specific spatial distribute on in the coastal waters. The most prevalent pulse types persisted for more than four years, emphasizing their capacity to adapt and survive in marine environments. Using PFGE analysis, marine isolates were compared with *Salmonella* serovar Senftenberg isolates from neighboring mussel-processing facilities and to other epidemiologically unrelated isolates from human, animal and feed sources. Comparison of the restriction patterns showed that indistinguishable PFGE types were present in the isolates from mussel-processing facilities and their surrounding marine areas, suggesting that the mussel processing is the main source for contamination with *Salmonella* Senftenberg in these marine environments. A molecular fingerprinting relationship was established between three shellfish isolates and a human isolate, which could be considered as preliminary evidence of infection caused by *Salmonella* Senftenberg associated with molluscan consumption. Nine strains isolated from these environments and showing diverse plasmids were sequenced by NGS (MiSeq): 68/8386, 17/6215, 54/6648, 57/6651, 15/6210, 17/7517, 16/8751, 68/9119, and 13/8748. The project consist in perform an in silico analysis of the genome data in order to answer the following questions: 1) Which plasmids (plasmidome) each of these strains carry?, 2) Are they the same?, 3) Are there any genes in those plasmids capable of conferring them the ability to survive in high saline environments?, 4) Are there other determinants on their chromosome that can confer them the ability to survive in high saline environments?, 5) Do these strains contain genes that confer resistance to antibiotics?, and 6) How different are they from other S. Senftenberg?

Rita Humeniuk, Ph.D.

Medical Countermeasures Initiative

Pediatric Clinical Pharmacology Staff

Office of Clinical Pharmacology

Office of Translational Sciences

Center for Drug Evaluation and Research (CDER)

Preceptor: Dionna Green, M.D.

Scientific and Professional Background

2008-2013	Post-Doctoral Fellow, National Cancer Institute, Laboratory of Cellular Oncology, National Institutes of Health
2003-2008	Doctor of Philosophy (Ph.D.), Cellular and Molecular Pharmacology, Rutgers, The State University of New Jersey
1997-2002	Master of Science and Engineering (M.Sc.), (M.Eng.), Molecular Biotechnology, University of Technology, Wroclaw, Poland

Research Interests

Rita has a broad research interest in drug development. As a postdoctoral fellow at the National Cancer Institute she studied stem cell biology and developed animal models of hematological malignancies. In her graduate research, she primarily focused on identifying novel mechanisms of drug resistance in cancer and exploring mechanisms of action of new drugs and drug combinations.

Commissioner's Fellowship Project Overview
Application of quantitative tools in deriving pediatric dosing for medical countermeasure products

FDA Regulatory Science Priority Area: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security

The project will involve (1) describing the past scientific and regulatory pathways used for labeling medical countermeasures for use in the pediatric population; (2) assessing the existing gaps in pediatric dosing for medical countermeasures; and (3) exploration of the role of quantitative tools such as modeling and simulation and physiology-based pharmacokinetics (PBPK) in establishing dosing of medical countermeasures for the pediatric population.

J. Paul Kirwan, Ph.D.

Office of Regulatory Affairs (ORA)

Winchester Engineering and Analytical Center

Preceptor: Cong Wei, Ph.D.

Scientific and Professional Background

2012-2013	Postdoctoral Fellow	University of Colorado School of Medicine, Aurora, CO
2006-2012	Ph.D. Biochemistry	University of Colorado School of Medicine, Aurora, CO
2002-2004	Research Assistant	Pharmacology, University of Colorado School of Medicine
2001-2003	M.S. Chemistry	University of Colorado, Denver, CO
1999-2001	Assistant Chemist	Midwest Research Institute (MRI Global), Kansas City, MO

Research Interests

- Protein/peptide engineering applications - therapeutic, vaccine, drug delivery, devices (hydrogel)
- Biophysical and computational analysis of molecular structure/surface interactions
- Computational modeling and experimental studies of surface interactions
- The relationship between molecular stability, structure, function, and disease states
- Modeling of transport phenomena, solute diffusion in complex matrices, drug delivery
- Development and regulation of biologics, *in vitro* diagnostics, and companion diagnostics
- Clinical trial design and review

Commissioner's Fellowship Project Overview

Modeling and surface analysis of the permeation of selected isotopes on food and packaging surfaces to enable rapid turnaround food sample analysis and consequence management decision making.

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

The 2011 nuclear power plant accident in Fukushima, Japan reaffirmed an urgent need for rapid screening analytical methods for the detection of surface radioisotope contaminants to inform consequence management and sample triage regulatory decision making in an emergency response to a radiological event. Our objective is to characterize selected isotope/surface interactions, both computationally and experimentally, to systematically determine the permeation rates of isotopes that penetrate food or packing surfaces. Our approach will include both, the modification of an existing algorithm describing the migration of packing material polymers into food, as well as spectroscopy/microscopy (e.g. Auger, SIMS, XPS) experiments of isotopes deposited on surfaces. An understanding of isotope permeation rates would be essential for the design of an efficient sample triage mechanism. To date, no such systematic analysis has been performed and no methodology has been established. The proposed methodology is also applicable to the evaluation of the safety of packing materials for food or medicine.

April Marrone, Ph.D.

National Center for Toxicological Research (NCTR)

Preceptors: Igor Pogribny, M.D., Ph.D.
and Frederick Beland, Ph.D.

Scientific and Professional Background

Education

2009:	Ph.D. Chemistry; University of Central Florida
2005:	BS Physics; University of Central Florida

Experience

2012-2013:	University of Pittsburgh Children's Hospital of Pittsburgh of UPMC, Senior Postdoctoral Associate
2009-2012:	Max-Planck Institute for Biophysical Chemistry; Postdoctoral Scientist
2006-2009:	University of Central Florida National Center for Forensic Science, Graduate Research Associate
2003 – 2005:	University of Central Florida Physics Dept., Research Scientist
2000 – 2003:	Lockheed Martin Space Operations, Computer Programmer

Research Interests

Dr. Marrone's general research interest is on microRNAs and how they relate to human disease. Increasing evidence shows that numerous biological responses involve a change in the microRNA expression profile. Thus, it is hypothesized that these small regulatory molecules offer great opportunities for early disease detection biomarkers and potential targets for therapies.

Commissioner's Fellowship Project Overview

Development and evaluation of a novel in vitro microRNA screening model system for the hazard identification of FDA-regulated products.

FDA Regulatory Science Priority Area: Modernize Toxicology to Enhance Product Safety.

Evaluating the carcinogenic risk of chemicals, including pharmaceuticals, is of great importance. Currently, there is no reliable technique for rapid *in vitro* identification of non-genotoxic carcinogenic compounds. Remarkable progress in the field of epigenetics provides a unique opportunity to incorporate epigenetics into carcinogen identification and safety assessment. The main goal of the CFP project is to develop a high-throughput *in vitro* microRNA screening assay for the identification of potentially carcinogenic substances to begin to have an alternative testing mechanism to the classical 2-year rodent carcinogenicity bioassay. In general, the incorporation of epigenetic technologies in cancer risk assessment promises to enhance substantially the efficiency of carcinogenicity testing.

Aftin Ross, Ph.D.

Center for Devices and Radiological Health (CDRH)

Preceptor: Suzanne Schwartz, M.D., MBA

Scientific and Professional Background

2012-2013	Whitaker International Postdoctoral Fellow, Karlsruhe Institute of Technology
2012	Ph.D. Biomedical Engineering, University of Michigan
2009	M.S.E Biomedical Engineering, University of Michigan
2007	B.S. Mechanical Engineering, University of Maryland Baltimore County

Research Interests

Aftin's graduate and postdoctoral work was focused on the surface engineering of polymers for stem cell culture and sensing/diagnostics applications. In particular, she worked on the surface modification of thin-film polymeric coatings in an effort to control the interactions of cells and proteins with these coatings. Currently, she is interested in the availability, safety, and efficacy of medical devices in the emergency preparedness workspace.

Commissioner's Fellowship Project Overview

Protecting Health Care Workers from Airborne Transmitted Disease via Use of Respiratory Protective Devices: A Gap Analysis of Regulatory Science in the Context of Current Practice and Regulatory Policy to Inform Medical Countermeasures for Pandemic Preparedness

FDA Regulatory Science Priority Area: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security

Medical countermeasures (MCMs) are drugs, biologics, and devices that can be used to safeguard public health against naturally occurring and manmade threats. Respiratory protective devices (RPDs) are an example of an MCM which play an important role in protecting health care workers (HCWs) employed in areas where patients may be infected with airborne transmitted diseases such as influenza. In the event of an influenza pandemic (such as H1N1 in 2009), the need for RPDs may far outpace the supply. This results in device shortages which poses a serious public health problem. Several approaches for increasing and extending the RPD supply have been proposed. However, these approaches lead to additional challenges in regulatory science, regulatory policy, and healthcare practice which must be comprehensively explored in order to bolster pandemic preparedness. The broad objective of this project is to enhance preparedness in the event of an airborne transmitted disease pandemic. This objective is accomplished by examining the current usage of RPDs and challenges encountered in this usage in healthcare delivery, identifying and addressing regulatory science knowledge gaps related to the use of RPDs, and utilizing the data/information collected to inform regulatory policies going forward.

Katie Segars, MS, Ph.D.

Microbiological Sciences Branch
Southeast Regional Laboratory
Office of Regulatory Affairs (ORA).

Preceptor: Irshad Sulaiman, MSc, MPhil, Ph.D.

Scientific and Professional Background

2008	State University of New York, University at Albany	B.S. Biological Sciences
2011	Georgia State University	M.S. Applied and Environmental Microbiology
2013	Georgia State University	Ph.D. Applied and Environmental Microbiology
2013	Georgia State University	Post-Doctoral Research Fellow

Research Interests

Dr. Segars' previous research experience involves development of targeted biological control agents, with a focus on the impact that environmental factors have on antimicrobial efficacy. Her other interests include the effect of external influences such as nutrient availability, temperature, pH, and other growth conditions on microbial metabolism. Current work will blend metabolic studies with gene expression to optimize pathogen detection.

Commissioner's Fellowship Project Overview
Method development for rapid detection of Cronobacter sakazakii.

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

Cronobacter sakazakii is an opportunistic pathogen that is fatal to nearly half of all neonates infected. Many past *Cronobacter* outbreaks have been linked to consumption of contaminated powdered infant formula. The current methodology for isolating *Cronobacter* from powdered infant formula is hindered by characteristically low colony counts in the formula, as well as lengthy procedures for cultivating the organism prior to identification at the genetic level. When susceptible populations, such as newborns, are exposed to a dangerous pathogen, rapid detection and identification of the organism are critical to patient survival rates and overall outcome. This research aims to improve recovery of *Cronobacter* isolates, as well as increase the efficiency and accuracy of identification through molecular genetic techniques.

Iwen Wu, Ph.D.

Multi-Center Fellowship in Regenerative Medicine

Center for Biologics Evaluation and Research (CBER)

Center for Devices and Radiological Health (CDRH)

Preceptors: Mercedes Serabian (CBER), Pakwai Au (CBER), Aric Kaiser (CDRH), and Elias Mallis (CDRH)

Scientific and Professional Background

2013 Ph.D. Biomedical Engineering, Johns Hopkins University

2008 B.S. Bioengineering- Biotechnology, University of California, San Diego

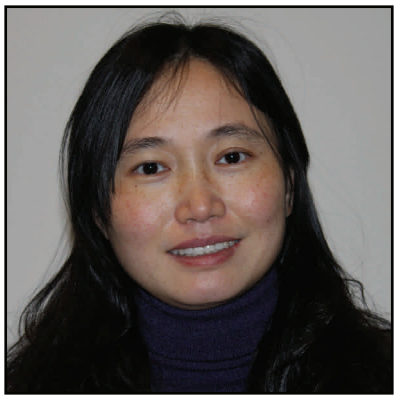
Research Interests

Iwen's research interests are in the area of biomaterials development and regenerative medicine. For her graduate studies, she developed an extracellular matrix-based biomaterial for soft tissue reconstruction. Additionally she investigated stem cell interactions with the extracellular matrix and how stem cell behavior is influenced by matrix properties. She has also evaluated the in vivo biocompatibility of extracellular matrix-based biomaterials using various animal models to assess volume persistence and tissue regeneration.

Commissioner's Fellowship Project Overview
Evaluation of the Immunogenic Potential of Cell-based Regenerative Medicine Products

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

Cell-based regenerative medicine products are intended to restore, replace, or regenerate damaged tissues and organs, thereby addressing a variety of unmet medical needs. One concern associated with the administration of cell-based RM products is the induction of an immune response generated by the patient to the RM product, which can render the product ineffective or result in adverse immunological reactions. Current approaches used to evaluate the immunogenicity of cell-based regenerative medicine products are often inconsistent and the extent to which this risk is assessed in both preclinical and clinical studies is unclear. Therefore, a systematic review of regulatory submissions is needed to document the approaches to immunogenicity assessment in order to identify patterns of consistency, as well as potential gaps that exist in the preclinical and clinical development programs for a regenerative medicine product. This review will inform the development of consistent, standardized strategies to evaluate the immunogenic potential of cell-based regenerative medicine products.



Pin Zhang, M.D., Ph.D.

Center for Biologics Evaluation and Research (CBER)

Preceptor: Elizabeth Sutkowski, Ph.D.

Scientific and Professional Background

2007 – 2011 Postdoctoral Fellow, National Institutes of Health (NIH)
2004 – 2007 Ph.D. Immunology, Shandong University, School of Medicine, China
2001 – 2004 M.S. Immunology, Shandong University, School of Medicine, China
1996 – 2001 M.D. Clinical Medicine, Taishan Medical University, China

Research Interests

Dr. Pin Zhang's current research focuses on clinical trial field, especially the adverse events analysis, database design and data management. Besides her clinical research background, she has experiences in immunology. She was interested in the regulatory T cells development and its function in the immune system. She was also interested in finding an effective way to induce antigen specific regulatory T cells *in vivo* to target autoimmune diseases and providing evidence for use of regulatory T cells in clinical trials. Her expertise includes clinical tri-als, immunology and a broad range of immunological and molecular biologi-cal techniques.

Commissioner's Fellowship Project Overview
Analysis of safety profiles across licensed vaccines

FDA Regulatory Science Priority Area: Harness Diverse Data through Information Sciences to Improve Health Outcomes.

Vaccine has been a medical milestone for preventing infectious diseases. There is very low risk-to-benefit ratio of vaccine, but the fear of negative side effects has discouraged many people from getting vaccinated, so the accurate information about the value of vaccines as well as their possible side effects will help people make in-formed decisions about vaccination. An important component of evaluating the safety of vaccines is the analysis of adverse events (AEs) experienced by the subjects enrolled in clinical trials. This project will involve exploratory analyses of AEs that have occurred in clinical trials of biologics license applications (BLA) and/or biologics li-cense supplements (BLS) across licensed vaccines. The clinical trials data will be combined together to expand the study population to analyze the trends of adverse events, especially the rare adverse events and adverse events of special interest.

FDA Commissioner's Fellowship Program

2013 Preceptors

Frederick Beland, Ph.D.

National Center for Toxicological Research (NCTR)

Background:

B.A., Colorado College
M.S., Montana State University
Ph.D., Montana State University

FDA Experience – 37 years

Research Interests:

Molecular toxicology, molecular carcinogenesis, genetics, and epigenetics.

Jeffrey Fisher, Ph.D.

Division of Biochemical Toxicology
National Center for Toxicological Research (NCTR)

Background:

Ph.D. Miami University, Oxford, OH, Zoology and Toxicology, 1987
M.S. Wright State University, Dayton, OH, Biology, 1979
B.S. University of Nebraska at Kearney, Kearney, NE, Biology, 1973

FDA Experience – 3 years

Research Interests:

• Development and application of physiological models for chemical and drug toxicological assessments of dose -responses, exposure profiles, and risk assessment.
• Development and application of biologically based models of the hypothalamic-pituitary-thyroid axis to evaluate hypothyroxinemia and hypothyroidism caused by chemical or drug exposure.

Narjol Gonzalez-Escalona, Ph.D.

Microbial Methods and Subtyping Branch
Division of Microbiology
Office of Regulatory Science (ORA)
Center for Food Safety and Applied Nutrition (CFSAN)

Background:

Ph.D.in Microbiology, 2004. University of Chile

Research Interests:

Development and validation of Real time PCR for the detection of Salmonella enterica Enteritidis in eggs.

Dionna Green, M.D.

Pediatric Clinical Pharmacology Group
Office of Clinical Pharmacology
Office of Translational Sciences
Center for Drug Evaluation and Research (CDER)

Background:

B.S. in Biology, 2001; M.D., 2005
Pediatric Training, 2008
Clinical Pharmacology Fellowship, 2009
FDA Commissioner's Fellowship Program, 2009-2011
Biohazardous Threat Agents and Emerging Infectious Diseases 2-Yr Certificate Program, 2011-2013

Total years of FDA employment: 3.5

Research Interests:

Pediatric drug development, pharmacogenomics, organ transplantation, medical countermeasure development

Aric Kaiser, M.S.

Center for Devices and Radiological Health
Office of Device Evaluation (CDRH)
Division of Orthopedic Devices

Background:

B.S., Biomedical Engineering, Case Western Reserve University, 1985
M.S., Mechanical Engineering, University of Cincinnati, 1987
FDA experience – since 1994

Research Interests:

Aric Kaiser, an expert biomedical engineer with experience in tissue mechanics and mechanical testing, has regulatory and scientific interests in the design and evaluation of products intended to treat orthopedic disorders. Of particular interest are tissue-engineered medical products (combination products) and devices intended to serve as functional replacements for the diseased or damaged tissue, e.g., products intended to repair/regrow damaged cartilage with functional tissue rather than implantation of synthetic materials as in total joint replacements. Recent work has focused on bone void fillers containing calcium salts, collagen and/or recombinant human proteins or synthetic peptides.

Sangeeta Khare, M.S., Ph.D.

Division of Microbiology
National Center for Toxicological Research (NCTR)

Background:

Ph.D. – Microbiology and Immunology, All India Institute of Medical Sciences, New Delhi, India
Post-Doctoral Fellow – Immunology and Microbiology, University of Saskatoon, Canada
Academic Positions – Veterinary Pathobiology, Texas A&M University, USA
Adjunct Faculty – Veterinary Pathobiology, Texas A&M University, USA

FDA Experience – 3 years

Research Interests:

We are chronically exposed through dietary and environmental exposures to trace chemicals of modern society including prescription drugs, pesticides and herbicides, additives, and invading enteric pathogens. The goal of my research is to describe the complex relationships and health consequences of these trace exposures on the commensal bacteria populations of the gastrointestinal tract (GIT).

I have used several models (in vivo, ex vivo and in vitro) and innovative technologies (omics approach, massive parallel sequencing, nanotechnology and systems biology modeling) to define gastrointestinal responses and identify biomarkers for cytotoxicity due to acute and chronic exposure (with biosafety level 2 and biosafety level 3 pathogens).

My ongoing research defines comparative patho-genomics studies of host-pathogen interaction and influence of pathogen virulence factors on the invasion and persistence of invading microorganism and commensal bacterial population. Another aspect of my research is to assess the interaction of nanoparticles with GIT. The outcome of this research will have a direct impact on the discovery of biomarkers, improved food safety and personalized treatment

Sanjai Kumar, Ph.D.

Division of Emerging and Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research (CBER)

Background:

2002- Present: FDA
1996- 2001: Chief, Blood Stage Malaria Research, Naval Medical Research Center and Adjunct Faculty, School of Public Health, Johns Hopkins University
1996 – 1986: Visiting Fellow and Visiting Scientist, National Institutes of health

Research Interests:

Molecular immunology, pathogenesis and detection of infectious agents particularly malaria and Babesia parasites. Special interest in understanding the molecular basis of malaria immunity and mediators of severe disease in experimental models and field studies. Assay development for detection of infectious agents in blood. Genomics studies on Babesia parasites to identify novel antigens for diagnostics and pathogenesis studies.

Elias Mallis

Office of Communication and Education

Center for Devices and Radiological Health (CDRH)

Background:

B.S. Electrical Engineering, University of Maryland at College Park

U.S. Food and Drug Administration, 1994-present

1994-2001 – Electrical Engineer, Gastroenterology/Renal Devices Branch, CDRH/ODE

2001-2009 – Branch Chief, Cardiac Electrophysiology/Monitoring Devices, CDRH/ODE/DCD

2009-2011 – Policy Analyst, Office of Device Evaluation, CDRH

2011-present – Director, Division of Industry and Consumer Education

Regulatory Interests:

Mr. Mallis currently serves as Director of the Division of Industry and Consumer Education in the Center for Devices and Radiological Health. In this role, Mr. Mallis leads the division whose mission is to educate stakeholders with understandable and accessible science-based regulatory information about medical devices and radiation-emitting electronic products. In his first 16 years at FDA in CDRH's Office of Device Evaluation, Mr. Mallis was responsible for the regulatory review and scientific evaluation of a variety of medical devices, which spanned the disciplines of gastroenterology, extracorporeal therapeutics, obstetrics/gynecology, cardiac diagnostic implants, and cardiac therapeutics, including novel biologics/device/drug combination products. Mr. Mallis has previously served as a preceptor for the Regenerative Medicine Program.

Igor Pogribny, M.D., Ph.D.

Division of Biochemical Toxicology
National Center for Toxicological Research (NCTR)

Background:

M.D., Ivano-Frankivsk Medical University
Ph.D., Kyiv National Medical University

FDA Experience – 16 years

Suzanne Schwartz, M.D., MB

Center for Devices & Radiological Health (CDRH)

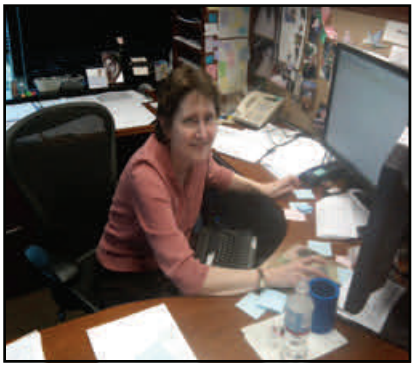
Program Background (MCM):

Medical countermeasures (MCM) are drugs, devices – including diagnostics – and other medical interventions that can mitigate the harmful effects of chemical, biological, radiological, nuclear (CBRN) threats as well as those from emerging infectious diseases.

At CDRH, the vision of the Emergency Preparedness/Operations and Medical Countermeasures (EMCM) Program is *to ensure that the American people have ready access to safe, effective and secure medical devices at all times – especially before and during response to any natural, accidental or intentional public health emergency.*

Research Interests:

Operational improvements across the MCM space; innovation and stakeholder collaboration for MCM development and deployment; MCMs for burn mass casualty incident; public health emergency preparedness & operations via all-hazards approach; building resiliency in medical devices to counter environmental threats from natural disasters such as extreme weather, and to protect against cyberthreats for which certain medical devices may be vulnerable.



Mercedes Serabian, M.S., DABT

Office of Cellular, Tissue, and Gene Therapies (OCTGT)
Center for Biologics Evaluation and Research (CBER)

Background:

B.S. (Biochemistry & Biology) Virginia Polytechnic Institute and State University
M.S. (Toxicology) The American University
DABT - Diplomate, American Board of Toxicology
1993-2002 – Toxicologist; FDA/CBER/OTRR
2002-Present – Branch Chief; FDA/CBER/OCTGT/DCEPT/PTB

Regulatory Interests:

Ms. Serabian is Chief of the Pharmacology / Toxicology Branch of CBER/OCTGT and would serve as Preceptor for this fellowship. As Branch Chief, she is responsible for overseeing the preclinical review, regulation, and policy development for all cell therapy, gene therapy, and tissue-engineered products regulated by CBER/OCTGT. She leads an experienced group of personnel with postdoctoral training in pharmacology, toxicology, biochemistry, biology, immunology, and biomedical engineering. The Branch is responsible for the regulatory review of all preclinical studies submitted to OCTGT to support the safe use of an investigational product in human trials. Ms. Serabian co-founded the CBER Pharmacology / Toxicology Working Group to facilitate interactions among CBER pharmacology/toxicology staff, and to promote discussions of scientific and regulatory issues regarding products (including preventive vaccines, blood products, and cellular and gene therapies) regulated by CBER. She also serves as a CBER representative to various committees within FDA, as well as national and international working groups; and initiated a series of interactions between CBER pharmacology/toxicology staff and members of the Special Biologics Expert Working Group of the Biotechnology Industry Organization (BIO), to discuss the preclinical testing of CBER-regulated biologics. In addition, she oversees the participation of reviewers in her Branch at intracenter, intercenter, interagency, national, and international meetings, workshops, and symposiums associated with cell therapy, gene therapy, and tissue-engineered products. Under her leadership, the draft guidance entitled, Draft Guidance for Industry: Preclinical Assessment of Investigational Cellular and Gene Therapy Products was released in November 2012[1]. She has served as a Preceptor in the Regenerative Medicine Fellowship Program and currently is a Preceptor in CBER.

Irshad Sulaiman, M.Sc., M.Phil, Ph.D.

Microbiological Sciences Branch
Southeast Regional Laboratory (SRL)
Office of regulatory Affairs (ORA)

Background:

Ph.D. – University of Delhi, India
M.Phil. – A. M. University, India
M.Sc. – A. M. University, India

FDA Experience – 4 and half years (2008-Present

Professional Experience:

2011-Present: Adjunct Professor, Department of Biology, Georgia State University, Atlanta, Georgia
2008-Present: Research Microbiologist, Southeast Regional Laboratory, FDA, Atlanta, Georgia
2003-2008: Research Scientist, Division of Scientific Resources, CDC, Atlanta, Georgia
1997-2003: Visiting Scientist, Division of Parasitic Diseases, CDC, Atlanta, Georgia
1996-1997: Research Fellow, Medical College of Georgia, Augusta, Georgia
1993-1996: Young Scientist, National Institute of Immunology, New Delhi

Research Interests:

Dr. Sulaiman joined the Microbiological Sciences Branch, Southeast Regional Laboratory, U. S. Food and Drug Administration, Atlanta, Georgia as a Research Microbiologist on October 12th of 2008, with over 16 years of research experience and expertise in the field of molecular genetics and its application in method development to detect and differentiate various human-pathogenic emerging infectious agents. Before coming to FDA, Dr. Sulaiman worked at the Centers for Disease Control (CDC) for eleven and half years from 1997 to 2008. Dr. Sulaiman obtained his PhD degree in 1992 to study Conservation Biology, Population Genetics and Ecology of Endangered Species from University of Delhi.

Dr. Sulaiman's research for over 20 years has focused on the molecular genetic characterization and rapid detection methods for human-pathogenic parasites (Cyclospora, Cryptosporidium, Giardia), bacteria (Cronobacter, Bacillus, Salmonella), viruses (orthopox, SARS, Hepatitis A), fungi (Microsporidia, Indicator fungal species from environmental swabs), and some pest species (the FDA "Dirty 22" species) responsible for the spreading of foodborne pathogens, from outbreak settings, routine surveillance and sporadic cases for their Detection, Prevalence, Epidemiology, Transmission Dynamics, Taxonomy, Phylogeny and Evolutionary Relationships of public health importance.

Dr. Sulaiman has published over 70 manuscripts in peer-reviewed journals with high impact factors, and written 4 book chapters in his area of expertise.

Elizabeth Sutkowski, Ph.D.

Division of Vaccines and Related Product Applications (DVRPA)
Office of Vaccines Research and Review (OVRR)
Center for Biologics Evaluation and Research (CBER)

Background:

B.A. – Chemistry, Manhattanville College
Ph.D. – Biochemistry, Georgetown University, School of Medicine and Dentistry
FDA Experience – 20 years

Research Interests:

The Preceptor is Chief of a Regulatory Review Branch in the CBER division responsible for the regulatory aspects of assuring the safety and efficacy of vaccines and related products. She has experience in the regulation of both investigational and licensed bacterial and viral vaccines for infectious disease indications with a focus on vaccines for seasonal and pandemic influenza and a special interest in novel vaccine adjuvants.

Stephen Torosian, Ph.D.

Winchester Engineering and Analytical Center (WEAC)
Office of Regulatory Affairs (ORA)

Background:

B.S. Microbiology ‘77, Ph.D. Microbiology ‘93, Prior to joining FDA in Jan. 2003, served as Faculty at the University of New Hampshire.

Research Interests:

Prior to joining FDA I conducted research in Cell Culture, Virology, Microbial Genetics and Select Agents. Research interests with FDA include rapid methods development with Select Agents in foods, virus in foods, high throughput molecular assays and methods as well as investigating nano potential for field capable real time food analysis.

Cong Wei, Ph.D.

Winchester Engineering and Analytical Center
Office of Regulatory Affairs (ORA)

Background:

Ph.D. in Chemistry, Yale University
M.S. in Chemistry, Boston University
M.S. in Electrical Engineering, University of Electronic Science and Technology of China
B.S. in Physics, Sichuan University, China

Industry experience – 7 years
FDA Experience – 9 years

Research Interests:

Develop quick turnaround and high throughput technologies and methodologies for analyzing FDA regulated products.