FDA Commissioner's Fellowship Program

Class of 2011

FDA Commissioner's Fellowship Program
2011 Fellows

FDA Commissioner's Fellowship Program
2011 Preceptors

FDA Commissioner's Fellowship Program
2011 Preceptors and Fellows by Center

CBER

Preceptor	Fellow
Michael Alterman	Kristin Schultz-Kuszak
Kimberly Benton	Jalal Sheikh
Karen Elkins	Jonathan Swoboda
Marian Major	Wendy Tan
Anita Richardson	Prakash Rath

CDER

Preceptor	Fellow
Gilbert Burckart	Jeremiah Momper
Tahseen Mirza	Ahsanul Haque
Anne Pariser	Gumei Liu

CDRH

Preceptor	Fellow
Nandini Duraiswamy	Clark Meyer
Markham Luke	Anh Nguyen
Elizabeth Mansfield and	Jacquline Yancy and
Katherine Serrano	Barbara Abrams
Scott McNamee	Jennifer Kelly
Megan Moynahan	Charles Haggart
Sithu Sudarsan	Yanna Kang

CFSAN

Preceptor	Fellow
Julie Kase	Alifiya Ghadiali
Y. Carol Shieh	Absar Alum

CTP

Preceptor	Fellow
Phil (Raymond) Yeager	Brian Erkkila

FDA Commissioner's Fellowship Program
2011 Preceptors and Fellows by Center, cont…

CVM

Preceptor	Fellow
O. Alberto Chiesa	Gajendiran Mahadevan
Renate Reimschuessel	Olgica Ceric

NCTR

Preceptor	Fellow
Jeff Fisher	Xiaoxia Yang
Beverly Lyn-Cook	Li Pang
Laura Schnackenberg	Katya Petrova

OC

Preceptor	Fellow
Vicky Seyfert-Margolis	Michael Mendicino and Shifu Zhao

ORA

Preceptor	Fellow
Aref El-Demerdash (KS)	Eric Chea
Gary Hartman (CA)	Subrat Rout
Sunee Himathongkham (CA)	Kimberly Anderson
Andrew Lin (CA)	Laurie Clotilde
Sean Linder (AR)	Ji-Young Park

Regenerative Medicine Project

Preceptor	Fellow
Elias Mallis, Jiyoung Dang, Mark Lee and Steven Oh	Cynthia Chang and Diana Yoon

FDA Commissioner's Fellowship Program

2011 Fellows

Barbara Demby Abrams, M.D., J.D.

Center for Devices and Radiological Health (CDRH)
Office of In Vitro Diagnostics

Preceptors: Elizabeth Mansfield, Ph.D. and
Katherine Serrano, B.S.

Scientific and Professional Background

2005-2011	Medical-Legal Consultant to Florida's Dept. of Health in the area of Disability Determinations and to Florida's Court System in the areas of Guardianship/ Incapacity and Mentally Retarded Criminal Defendants
2002-2005	J.D., Florida State College of Law
1989-2002	Private Practice of Primary Care Clinical Pediatrics
1986-1989	Pediatric Internship and Residency at Cleveland Metropolitan General
1981-1986	M.D., Boston University School of Medicine
1979-1986	B.A. in Medical Science, Boston University

Research Interests

My diverse educational and professional experience enables me to bridge different fields. I am particularly interested in improving public health policy by helping legal professionals understand medical/scientific issues, helping medical/scientific professionals understand regulatory issues, and helping FDA stakeholders and the public understand medical, scientific, and regulatory issues.

Commissioner's Fellowship Project Overview

Developing guidance documents for research use only/investigational use only components in in vitro devices and risk-based classification of novel in vitro devices

My project is part of a broader CDRH initiative to develop greater transparency in its approach to regulatory decision making for product approval. I will be working on two guidance documents. The first will focus on the appropriate promotion and marketing of research use only and investigational use only components. The second will involve explaining how FDA considers risk for novel *in vitro* diagnostic (IVD) devices for the purpose of device classification. My project will contribute to the FDA's mission by providing information to stakeholders on FDA's thinking regarding IVD products. Providing greater transparency on how CDRH makes classification decisions and clarifying the appropriate promotion and marketing of products advances regulatory science and benefits the manufacturers of medical devices, the laboratories and health care providers who use the medical devices, and the public.

Absar Alum, Ph.D.

Center for Food Safety and Applied Nutrition (CFSAN)
FDA Moffett Center, Bedford Park, IL

Preceptor: Y. Carol Shieh, Ph.D.

Scientific and Professional Background
Ph.D. — Environmental Microbiology — University of Arizona, 2001
Faculty Research Associate, 2001-2006
National Science Foundation Water Quality Center at Arizona State University
Assistant Professor Research, 2006-2011
Civil, Environmental and Sustainable Engineering, Arizona State University

Research Interests
My research interest is in the area of health related environmental microbiology with primary focus on the survival, transport, and control of microbial pathogens in various environmental matrices specifically water and food. I have extensive experience in the application of cell culture and molecular techniques for the detection of pathogens.

- Rapid methods for the detection of pathogens in food and water
- Methods for concentrating pathogens in food and water

Commissioner's Fellowship Project Overview
Development of a Method to Concentrate Norovirus in Foods and Evaluation of Cell Culture System for Virus Propagation

In the US, enteric viruses are responsible for 59% of the total foodborne gastroenteritis outbreaks. Human noroviruses are a significant cause of viral gastroenteritis in the US and around the world. Globally, more than 50% of the viral gastroenteritis outbreaks are caused by human noroviruses. Due to their highly contagious nature, noroviruses are classified as category B biodefense agent. Efficient and rapid methods for the concentration and detection of infectious viruses in foods are an urgent need under the FDA's food safety mandate.

We plan to develop a rapid method that can be performed in a routine microbiology laboratory setting to concentrate low levels of noroviruses in variety of fresh produce matrices. In addition we plan to evaluate various factors that facilitate norovirus attachment and infection of mammalian cells cultures.

Kimberly M. Anderson, Ph.D.

Office of Regulatory Affairs (ORA)
San Francisco District Office, Alameda, CA

Preceptor: Sunee Himathongkham, Ph.D., D.V.M., M.P.V.M.

Scientific and Professional Background

2006-2011	Postdoctoral Fellow, Loyola University Medical Center, Maywood, IL Advisor: Professor Tarun B. Patel
2004-2006	Postdoctoral Fellow, Children's Memorial Research Center, Chicago, IL Advisor: Dr. Eric G. Bremer
1998-2004	Graduate Student, Tulane University, New Orleans, LA Mentors: Professor Yu-Teh Li and Dr. Su-Chen Li

Research Interests

- Development of rapid high-throughput assays for the isolation and identification of bacterial foodborne pathogens
- Investigate the contribution of stress initiated during food processing on the activation of bacterial resistance genes
- Isolation and characterization of biomedically useful enzymes from bacterial sources

Commissioner's Fellowship Project Overview

Rapid Molecular Typing of Shiga Toxin-Producing Escherichia coli Using the Automated DiversiLabÔ Repetitive-Sequence-Based PCR System

The length of time invested in microbial source tracking is a key factor in the ability of food regulatory agencies to assess foodborne outbreaks in real-time. Although, the discriminatory power of Pulsed Field Gel Electrophoresis (PFGE) for molecular subtyping is well documented, the PFGE process is labor-intensive and time-consuming. Rapid PCR-based typing methods may prove invaluable tools for complimenting the discriminatory power of PFGE, and there is great interest in using the DiversiLab rep-PCR system for microbial genotyping. The goal of this CFP study is to use the DiversiLab system to characterize a battery of shiga toxin-producing *E. coli* (STEC) isolates and determine whether rep-PCR can differentiate between and among known PFGE-subtypes. We will not only examine the reproducibility and typing ability of the automated DiversiLab rep-PCR system for STEC, but also create a library of rep-PCR patterns from well-characterized STEC isolates. In addition to this, our project will assess the DiversiLab rep-PCR system's ability to discriminate among STEC isolates by comparing results to those obtained with the 'gold standard' PFGE method. The findings of this project may improve the ability of regulatory agencies to detect and respond to food safety problems by facilitating the identification of microbial contaminants during outbreaks.

Olgica Ceric, Ph.D.

Center for Veterinary Medicine (CVM)

Preceptor: Renate Reimschuessel, Ph.D.

Scientific and Professional Background

07/2006	Ph.D. University of Belgrade, Serbia. Faculty of Veterinary Medicine, Department of Food Hygiene and Technology.
2004-2006	Management Representative (Quality Control Manager). Veterinary Specialists Institute "Pancevo", Pancevo, Serbia.
2000-2006	Associate, Serology. Veterinary Specialists Institute "Pancevo", Pancevo, Serbia.
07/2001	M.S. University of Belgrade, Serbia. Faculty of Veterinary Medicine, Department of Food Hygiene and Technology.
1996-2000	Associate, Food Laboratory. Veterinary Specialists Institute, "Pancevo", Pancevo, Serbia.
06/1996	B.S. University of Belgrade, Serbia. Faculty of Veterinary Medicine, Department of Food Hygiene and Technology.

Research Interests

I have 10 years of combined experience in veterinary diagnostics and food microbiology. My Master's thesis research interests were related to sensory analyses of chicken meat. My Ph.D. research was focused on determination of factors significant for presence of arsenic and heavy metals in snail tissues. My recent research interests are related to investigating potential problems with FDA/CVM regulated products-animal foods and animal drugs.

Commissioner's Fellowship Project Overview

Investigation of etiology of Chicken Jerky Treat related renal failure and Fanconi syndrome in dogs

In September of 2007, FDA issued a cautionary warning regarding chicken jerky products imported from China to consumers, and a Preliminary Animal Health Notification in December of 2008. The number of complaints dropped off during 2009 and 2010, but in 2011 there is an increase in the number of complaints of dog illnesses associated with consumption of chicken jerky treats. Signs reported in the complaints include decreased appetite; decreased activity; vomiting; diarrhea, sometimes with blood; increased water consumption and/or increased urination. In some cases, blood tests indicate kidney failure (increased urea nitrogen and creatinine), occasionally coupled with Fanconi syndrome (increased urinary glucose with normal blood glucose). FDA, in collaboration with several veterinary diagnostic laboratories in the U.S., is working to determine why these products are associated with illness in dogs. To date, despite chemical and microbial testing, scientists have not been able to determine a definitive cause for the reported illnesses. The objective of our project is to test chicken jerky products focusing on agents known to cause kidney failure/Fanconi syndrome

Cynthia J. Chang, D.Phil.

Regenerative Medicine Project
Center for Devices and Radiological Health (CDRH)
Center for Biologics Evaluation and Research (CBER)

Preceptors:
Jiyoung M. Dang, Ph.D. (CDRH), Mark H. Lee, Ph.D. (CBER), and
Elias Mallis, B.S. (CDRH)

Scientific and Professional Background

2011 D.Phil. Orthopaedic Surgery
University of Oxford & National Institutes of Health (NIH) collaborative program
2006 B.S. Bioengineering
Rice University, Houston, TX

Research Interests

My research background lies in tissue engineering and regenerative medicine, with a focus on musculoskeletal and orthopaedic applications. My scientific interests also include stem cells and differentiation, three-dimensional cell culture, mechanobiology, and biomaterials. For my doctoral research, I investigated the regenerative mechanisms behind the surgical bone lengthening procedure of distraction osteogenesis (DO), a unique example of the formation of new, organized tissue in adults caused by mechanical strain. My work involved a mouse model and an *in vitro* three-dimensional cell-scaffold construct model to provide basic information about how cells respond to mechanobiological cues in their environment.

Commissioner's Fellowship Project Overview

Cross-center identification of standards to enhance the premarket review process for scaffold-based products, such as surgical mesh devices and cell-scaffold engineered combination products

In the evaluation of the safety and efficacy of a medical product, preclinical testing is required to demonstrate that the product will perform appropriately in the clinical setting. For different products in a single product class, many performance requirements will be the same. As a result, the test methods and requirements are often similar, and may be based on published consensus standards, such as standard test methods. The objective of this project is to facilitate the premarket evaluation of surgical mesh devices, through the assessment and promotion of standards useful to performance testing of these products. Because regenerative medicine (RM) products include scaffold components that are similar in materials and function to surgical mesh devices, this project will have a broader impact in enhancing the premarket evaluation process for scaffold-based RM products.

Eric K. Chea, Ph. D.

Office of Regulatory Affairs (ORA)
Lenexa, KS

Preceptor: Aref El-Demerdash, Ph. D.

Scientific and Professional Background

Eric Chea received his B. Sc. in Biotechnology with minors in Chemistry and Physiology in 2006 from California State Polytechnic University, Pomona. He worked in the laboratory of Professor Vasu Dev undertaking the isolation and characterization of volatile organic compounds from indigenous California plants. As an intern at the Metropolitan Water District of Southern California, he was involved in a project led by Dr. Paul Rochelle and Dr. Anthea Lee to characterize bacterial biofilm populations in water treatment pilot plants through cloning and identification of 16S rRNA genes. Later, as a Howard Hughes Medical Institute Apprentice in the laboratory of Professor Dennis Livesay, he demonstrated that the *closeness centrality* metric is a viable way to predict catalytic sites.

Eric received his Ph. D. in 2011 from the Weill Cornell Graduate School of Medical Sciences working on the chemical synthesis of vaccine saponin adjuvants in Professor David Gin's group at the Memorial Sloan–Kettering Cancer Center. There he developed a 25-step synthetic route to immune potentiating saponins and discovered key structural features of saponins that influence adjuvant activity. The application of these guidelines has led to the successful development of the first set of saponin adjuvant chemical probes including the first radiolabelled, fluorescently labeled, and photo-affinity probe.

Research Interests

Eric is interested in using his interdisciplinary science background and expertise in synthetic chemistry for the benefit of human health. He wishes to apply his knowledge in bench-top science to all aspects of regulatory science.

Commissioner's Fellowship Project Overview

The development of a high throughput quantitative screen for adulterants in dietary supplements.

There have been close to 100 cases of dietary and herbal supplements that have been adulterated with phosphodiesterase (PDE) inhibitors. Taking PDE inhibitors unknowingly can pose significant health concerns for consumers who take nitrates (*i.e.* diabetic patients), as it can lower blood pressure to dangerous levels. Further complicating the matter are recent discoveries that some male sexual enhancement supplements contain PDE inhibitors with slight chemical modifications, which are likely being done to elude detection. As the number of dietary supplements entering the market increases to meet higher U.S. demand, the FDA will be faced with the challenge of protecting consumers from supplements that contain pharmaceutical ingredients. To help solve this Eric will synthesize a library of PDE inhibitor analogues and use this library to develop a high throughput method to screen dietary supplements for adulteration. He hopes to continue his career by using his expertise in synthetic chemistry to complement the analytical expertise at the ORA.

Laurie M. Clotilde, Ph.D.

Office of Regulatory Affairs (ORA)
San Francisco District Office, Alameda, CA

Preceptor: Andrew Lin, Ph.D.

Scientific and Professional Background

2008 - 2011 Research Biologist, USDA - ARS
2004 - 2008 Ph.D. Cellular and Molecular Biology, University of Nevada - Reno
2003 - 2004 M.S. Animal Sciences, University of Nevada - Reno
1999 - 2003 B.S. Biology, University of Nevada - Reno

Research Interests

My current research interests are in the area of microbial food safety, specifically focusing on developing faster detection methods for Shiga toxin - producing *Escherichia coli* (STEC). While I was at the USDA, I developed a macro - and microbead - based immunoassay for detecting different STEC serogroups and their Shiga toxins in various food matrices. My doctoral work focused on exploring the relationship between STEC prevalence and pre - harvest control measures to improve safety of cattle and their products, and identifying the molecular aspects of the recovered STEC isolates.

Commissioner's Fellowship Project Overview

Detection of Shiga toxin-producing Escherichia coli.

Because of the increase of outbreaks caused by non-O157 Shiga toxin-producing *Escherichia coli* (STEC), facilitating and speeding the detection of those organisms in contaminated foods is becoming extremely important. Therefore, we propose to compare and improve the efficiency of a 10-Plex PCR-based Luminex assay (*E. coli* serogroups O26, O45, O91, O103, O111, O113, O121, O128, O145, and O157), a 9-Plex antibody based Luminex assay (Shiga toxins 1 and 2 [Stx1 and Stx2], *E. coli* serogroups O26, O45, O103, O111, O121, O145, and O157), and a newly developed agar (SHIBAM) to the methods used in the FDA-Bacteriological Analytical Manual (BAM; Chapter 4a). These different assays have been previously developed by the Principal Investigator and/or her preceptor and will be further tested in shredded cheese and sprouts. Using the Luminex technology present many advantages: 1) The multiplexed format (up to 100 analytes) will save time, reagents, and test sample; and 2) Many Food and Drug Administration (FDA), Food Safety and Inspection Service (FSIS), and Food Emergency Response Network (FERN) laboratories currently utilize the Luminex platform for other assays. Therefore our assay would be directly transferable and implemented by these laboratories. Also an agar capable of more rapidly differentiating STEC from background organisms will shorten the isolation process. We will also explore the possibility of using Raman spectral fingerprinting for rapid identification of bacterial isolates.

Brian E. Erkkila Ph.D.

Center for Tobacco Products (CTP)
Office of Science

Preceptor: Raymond Yeager, Ph.D.

Scientific and Professional Background

2008-2011	Post-Doctoral Associate, National Institutes of Health (NICHD)
2007-2008	Post-Doctoral Associate, University of Texas Health Science Center at San Antonio (UTHSCSA)
2007	Ph.D. Neurobiology, University of Alabama at Birmingham
2000	B.A. Neuroscience, The Johns Hopkins University

Research Interests

My research focus has mainly been the structure, function and pharmacology of neurotransmitter receptors. My graduate work focused on the biophysical mechanism by which pesticides and other compounds modulate nicotinic and GABAergic ligand-gated ion channels. While a post-doctoral associate at the NIH, I broadened my scope to examine how this receptor modulation influenced interneuron migration during development. I hope to build upon this molecular, biophysical and developmental knowledge base to further the scientific and regulatory mission of the Food and Drug Administration.

Commissioner's Fellowship Project Overview

An Assessment of the Risks Associated with Childhood Exposure to Environmental Tobacco Smoke

In 2009 the Family Smoking Prevention and Tobacco Control Act (TCA, 2009) gave the Food and Drug Administration (FDA) regulatory authority over "the manufacture, distribution and marketing of tobacco products to protect public health." This legislation mandates CTP to minimize the risks associated with tobacco products in both users and **non-users**. Children comprise a population particularly susceptible to the effects of second-hand or "environmental tobacco smoke" (ETS), and for that reason it is necessary to conduct a lifestage-based risk assessment of ETS constituents. My CFP project will be to conduct a risk assessment of ETS constituents to determine the nature and probability of adverse health effects in children. Priority will be given to those constituents which have been deemed "Harmful or Potentially Harmful" by CTP, and the assessment will examine risks at several developmental stages (infant, child, adolescent).

Alifiya H. Ghadiali, Ph.D.

Center for Food Safety and Applied Nutrition

Preceptor: Julie A. Kase, Ph.D.

Scientific and Professional Background

2005-2009	Postdoctoral Fellow, University of Medical and Dentistry of New Jersey
2001-2005	Ph.D. Veterinary Preventive Medicine, The Ohio State University
1998-2001	Research Co-ordinator, Medical Research Council, United Kingdom and Society for Natal Effects on Health in Adults, India
1996-1998	M.Sc. Biochemistry and Clinical Nutrition, University of Mumbai, India
1993-1996	B.Sc. Microbiology and Biochemistry, University of Mumbai, India

Research Interests

Intricacies of biological science and disease have always intrigued me. This interest has grown into a deeper appreciation for the many challenges that impact control and eradication of infectious diseases. I am excited at the prospect of using revolutionary research and new technology to intervene and change the outcome of the diseases. I intend to pursue a career in a multi-disciplinary and interactive setting where I will have the opportunity to apply my training in veterinary medicine, public health, genetics and molecular epidemiology of bacterial pathogens. My overall career objective is to contribute to a better understanding of molecular pathogenesis of infectious agents. My primary research interests include comparative genomics, high-throughput genotyping, and drug resistance evolution. I have over ten years of experience in bacterial fingerprinting, molecular epidemiology, and diagnostics and therapeutics research related to emerging and biodefense pathogens.

Commissioner's Fellowship Project Overview

Recommendations for laboratory surveillance and screening of pathogenic Escherichia coli in food products using molecular methods.

Incidences of food borne outbreak caused by non-O157 shiga toxin-producing *Escherichia coli* (STEC) has increased recently. Six serogroups have been identified as clinically prevalent. However, other serotypes can and have caused severe illness. Current methods are unable to identify pathogenic non-O157 STEC due to lack of knowledge about which virulence factors (in addition to shiga toxin) are essential to make an STEC harmful to humans. To address this problem, we propose to define the genetic characteristics that are most commonly associated with human disease. The Food and Drug Administration (FDA) currently has no regulatory position to address the presence of non-O157 strains in foods, mostly due to the difficulties in assessing the pathogenicity of the STEC found in food products. This project will address part of this obstacle by identifying the STEC genetic profile that is most frequently linked to human illness and thereby, supporting the FDA's commitment to ensuring that America's food supply continues to be among the safest in the world.

Charles Haggart, Ph.D.

Center for Devices and Radiological Health (CDRH)

Preceptor: Megan Moynahan, M.S.

Scientific and Professional Background

2010-2011	CVRC Postdoctoral Fellow, University of Virginia
2010	Ph.D. Biomedical Engineering, Columbia University
2005	M.S. Biomedical Engineering, Columbia University
2003	B.S. Biomedical Engineering, University of Wisconsin-Madison

Research Interests

My primary scientific interests are focused on structural, metabolic, and functional remodeling of the heart in response to both physiologic and pathologic stimuli. My doctoral work aimed to identify both the specific mechanical signals responsible for triggering hypertrophic growth and remodeling of cardiac muscle as well as the downstream transcriptional effects of an altered mechanical environment (e.g., stress and strain). Most recently, I built genome-scale computational models of cardiac metabolism in both normal and heart failure states. A common theme between these two lines of work has been an interest in leveraging high-throughput 'omics data and quantitative methods to understand the complexity of cardiac physiology, biology, and metabolism.

Commissioner's Fellowship Project Overview

U.S. Medical Device Innovation (2000-2011): An Analysis of Regulatory Decision Points and Total Time-to-Market for PMA and De Novo Devices

Medical device innovation occurs rapidly and continuously, with great potential to positively impact public health in the United States. While most innovation is broadly incremental in nature, an important minority tends to positively disrupt the standards of care for treating and diagnosing disease. The faster that safe and effective, disruptive innovations are approved for broad clinical use, the sooner their positive effects on public health will be realized. The degree to which CDRH regulatory policies and processes either promote and/or inhibit this disruptive innovation has been speculated upon by external stakeholders, but has not been measured or analyzed with any scientific rigor. The central aim of my project is to build a regulatory historical database of disruptive medical device innovation and analyze this data so that we may 1) gain a greater understanding of CDRH's past regulatory performance on the most innovative medical devices and 2) identify those attributes of premarket submissions for innovative devices that exhibit a disproportionately large impact on the total time from FDA's first engagement with the device (sponsor) to full marketing approval of the device. I will also attempt to quantify the impact of CDRH regulatory decision making on medical device innovation.

Ahsanul Haque, RPh, Ph.D., RAC

Center for Drug Evaluation and Research (CDER)
Division of Drug Product Quality Research

Preceptor: Tahseen Mirza, Ph.D.

Scientific and Professional Background

2002-2011: Licensed Pharmacist (Florida & Virginia)
2000-2001: Post-doctoral Associate, University of Florida, Gainesville, Florida
1998-2000: Post-doctoral Associate, Virginia Tech, Blacksburg, Virginia
1994-1998: Ph.D, Bio-analytical Chemistry, College of Pharmacy, University of Georgia, Athens, Georgia

Research Interests

I did my Ph.D and post-doctoral research in the areas of analytical method development and validation of small molecules using HPLC/UV, Capillary Electrophoresis, GC/MS, LC/MS/MS and solid phase extraction. My research interests are in the following areas-

Determination of Bio-equivalency between Brand and Generic drugs
Correlation between *in-vitro* dissolution and *in-vivo* performance of drug products
Develop tools and standards to accelerate generic drug approvals
Harmonization of Regulatory guidance between FDA, EMA, ICH and WHO

Commissioner's Fellowship Project Overview
Development of in vitro models for the prediction of in vivo food effect on drugs

For some drugs especially those belonging to BCS Class 2 and Class 4, the bioavailability (efficacy) and safety may be impacted due to the co-administration of food. For example, the bioavailability of a low solubility (lipophilic) drug may increase significantly if it is co-administered with a full fatty meal as opposed to giving the drug only with water or light meal. The significance of food effect on the bioavailability of drugs is well recognized by clinicians and it is studied very early in the drug development process. The project is aimed at developing bio-relevant *in vitro* methods along with physiologically based absorption models by utilizing GastroPlus™ simulation software in the prediction of food effect.

Yanna S. Kang, Ph.D.

Center for Devices and Radiological Health (CDRH)

Preceptor: Sithu Sudarsan, Ph.D.

Scientific and Professional Background
2009-2011 Postdoctoral Fellow, National Institutes of Health
2009 Ph.D. Intelligent Systems, University of Pittsburgh, Pennsylvania
2003 M.S. Computer Science, Northeastern University, China
2000 B.S. Computer Science, Northeastern University, China

Research Interests
My general research interests are in spatio-temporal data mining and text mining. In particular, I am interested in applying techniques from machine learning, probabilistic modeling, and Bayesian statistics to biomedical and healthcare-related research. As a Commissioner's Fellow, I am excited to have the opportunity to work with FDA scientists to turn the FDA's vast volume of regulatory data into knowledge that can be used to protect and improve public health.

Commissioner's Fellowship Project Overview
Medical Device Adverse Event Labeling (MEDAL) – An Automated Text Mining Approach

Analysts at CDRH study Medical Device Reports (MDRs), which are adverse event (AE) reports related to medical devices, for identifying safety signals. These signals could be divided into two categories for an arbitrary device *D*: (i) a deviation relative to the historical baseline behavior between *D* and a known AE associated with it, e.g., a spike in the number of MDRs for *D* and a known AE in comparison with the past, and (ii) a previously unknown AE associated with *D*.

To identify the two types of safety signals described above, one needs to first classify a MDR as having information about a known event or an unknown, de novo event, for *D*. We define a known adverse event and an unknown event associated with *D* as a **labeled event** and an **unlabeled event**, respectively. We call this classification process **Medical Device Adverse event Labeling** (**MEDAL**). At present there is no tool that is available to help analysts to do MEDAL. This process, if done manually, is labor-intensive and time-consuming because the number of documents requiring study and analysis is increasing rapidly. Therefore, there is an urgent need to develop tools for efficient labeling. Using text mining techniques information related to adverse events can be automatically identified from existing resources like pre-market submissions.

This project aims to make use of pre-market submissions to identify known adverse events as provided in their warnings, contra-indications, precautions, etc. and use that information as a reference to label incoming MDRs. In this study, I will explore different text mining techniques and build a framework to automatically identify known adverse events.

Jennifer Kelly, Ph.D.

Center of Devices and Radiological Health (CDRH)

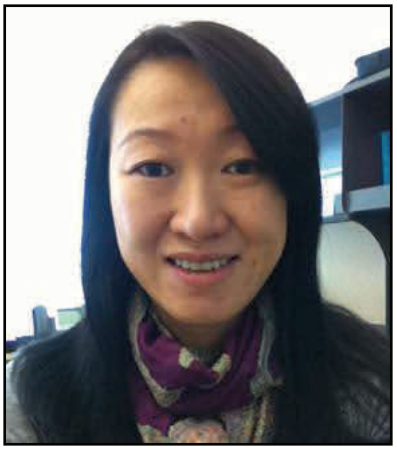
Preceptor: Scott McNamee, Ph.D.

Scientific and Professional Background
2009 – 2011 NRC Postdoctoral Fellow – Polymers Division/MML/NIST
2008 – 2009 Postdoctoral Research Assistant – Polymers Division/MML/NIST
2002 – 2008 Ph.D. Chemistry – University of North Carolina, Chapel Hill
1997 – 2002 B.S. Chemistry, B.A. German – Virginia Polytechnic Institute and State University

Research Interests
My primary research interests have included polymer and materials science and their applications in nanotechnology and medicine. Previous research efforts focused on investigating block copolymer thin films and controlling their self-assembly. These films can be utilized from templating applications used in the microelectronics industry to directing the placement of nanoparticles for smart coatings. In my postdoctoral work, compositional and thermal gradient techniques helped investigate surface & interfacial interactions in rapid fashion. My PhD thesis focused on the synthesis of novel fluorinated elastomers and their utility to advance innovation for drug delivery platforms. I utilized this platform to fabricate monodisperse, shape and size specific nanoparticles comprised of various proteins, enzymes, and antibodies for personalized medicine.

Commissioner's Fellowship Project Overview
The Effect of Extreme Weather Events on the Integrity and Safety of Medical Devices and Guidance toward Mitigating Future Challenges

The 21st century has brought on a record number of extreme weather events including hurricanes, tsunamis, wild fires, and extreme flooding to name a few. My CFP project will investigate the effects extreme weather events have on the integrity and safety of medical devices. Potential implications on medical devices will be examined throughout their manufacturing chain, transport, storage, and final use. Along with the manufacturing chain, this project will explore extreme weather conditions from a materials structure-property relationship as well as from the quality systems program currently in place. Identifying and assessing risks that extreme weather poses on medical devices and distinguishing current standard testing will prove instrumental to this project. The devices prone to the most risk under these conditions will be identified. Public and industrial outreach will help shape guidance developed to mitigate future challenges and risks under these extreme weather events.



Gumei Liu, Ph.D.

Center for Drug Evaluation and Research (CDER)

Preceptor: Anne Pariser, M.D.

Scientific and Professional Background

2010-2011	Senior Research Associate, Duke University
2007-2010	Postdoctoral Associate, Duke University
2005-2007	Postdoctoral Scholar, University of Iowa
2005	Ph.D. Neurobiology, University of Iowa
1999	M.D. Harbin Medical University, China

Research Interests

With training in both clinical medicine and basic science, I have always been interested in treatment development for unmet medical needs. My previous research has focused on developing novel therapies for central nervous system manifestations of rare disorders including lysosomal storage diseases, spinocerebellar ataxia and epilepsy. I hope to parlay my clinical and basic research experience to regulatory science while working at CDER.

Commissioner's Fellowship Project Overview

The role of natural history studies in drug development for rare diseases

Rare diseases (RD) have considerable unmet medical needs and few of them are well understood. An understanding of a rare disease's natural history (NH) is an important element for clinical trial design and outcome assessment for RD product development. In contrast to many common diseases, there often is little existing knowledge on the disease natural history for most RD, which makes NH studies of particular value in the support of RD product development. The goal of my CFP project is three-fold: 1) To establish a NH database for marketing applications for rare diseases reviewed by CDER from 2006 to 2011; 2) To identify key factors in NH studies that contribute to the clinical drug development for rare diseases; 3) To develop a framework on how well-conducted NH studies may facilitate drug development for rare diseases.

Gajendiran Mahadevan, Ph.D.

Center for Veterinary Medicine (CVM)

Preceptor: Oscar (Alberto) Chiesa, D.V.M., M. S., Ph.D.

Scientific and Professional Background

2004-2007 Senior Research Associate, Vanderbilt University, Nashville, TN.
2000-2004 Postgraduate Researcher, University of California, Los Angeles, CA.
1998-2000 Postdoctoral Research Fellow, Indiana University School of Medicine, IN.
1997-1998 Research Associate, Indian Institute of Chemical Biology, India.
1996-1997 Research Fellowship from International Brain Research Organization
1992-1996 Senior Research Fellow, Indian Institute of Chemical Biology, India.
1990-1992 Junior Research Fellow, Jadavpur University, India
1989-1990 Analytical Chemist, Health Line Pvt. Ltd., Bangalore, India
1998 Ph.D. (Pharmacology), Jadavpur University, India
1992 Master of Pharmacy, Jadavpur University, India
1990 Bachelor of Pharmacy, Annamalai University, India

Research Interests

For more than a decade, I have been working on *in vitro* and *in vivo* single neuron recordings from discrete brain regions (cortex, striatum, substantia nigra) and lumbar spinal cord of various neurodegenerative movement/motor disorders such as Parkinson's disease, Huntington disease, tardive dyskinesia, and stroke with a primary focus on neurophysiology and neuropharmacology. My research interest also includes pharmacokinetic and biopharmaceutical studies of pharmaceutical dosage forms and laser (infra-red) stimulation of mammalian neuronal tissue.

Commissioner's Fellowship Project Overview

Determination of antimicrobial drug concentrations in intestinal tissues and digestive secretions from treated steers. An initial phase to correlate antimicrobial drug concentrations in plasma and digestive secretions.

My fellowship project focuses on the determination of antimicrobials concentration of intestinal tissues and gastrointestinal fluid secretions from the duodenum, jejunum, and ileum of antimicrobial treated steers using a rapid and highly-sensitive Liquid Chromatography-Mass Spectroscopy/Mass Spectroscopy method. Antimicrobials have been extensively used in food-producing animals for number of purposes including growth promoters, therapeutics, prophylactic, and metaphylaxis. This may promote the selection of antimicrobial drug-resistant bacteria that in turn could persist in food products and the environment. The lack of data revealing actual concentrations of antimicrobials within the intestinal tissue/fluids that is exposed to gut flora of animals and the development of antimicrobial resistance warranted this present study.

Michael Mendicino, Ph.D.

Office of the Commissioner, Office of the Chief Scientist,
Office of Regulatory Science and Innovation

Preceptor: Vicki Seyfert-Margolis, Ph.D.

CBER OCTGT Mentors: Steve Bauer, Ph.D. and Keith Wonnacott, Ph.D.

Scientific and Professional Background

Professional

2011	R & D Program Manager, Regenerative Medicine, Avita Medical Ltd., Northridge, CA
2010-2011	Scientist, Immunology/Cell Therapy, Dept. of Regenerative Medicine, Athersys Inc., and Investigator, Biology/Immunology, National Center for Regenerative Medicine, Cleveland, OH
2009	Consultant, VT Business Technology Center, Blacksburg, VA
2006-2010	Senior Research Associate, Revivicor, Inc., Blacksburg, VA

Education

2007-TBD	M.B.A. (AACSB accredited), Radford University, Radford, VA (part-time)
2003-2006	Strategic Training Program in Regenerative Medicine - Certificate
1999-2006	Ph.D., Department of Immunology, University of Toronto, Toronto, Canada
1995-1999	B.Sc. (Honors), University of Toronto, Toronto, Canada; Specialist: Molecular Genetics and Molecular Biology/Major: Human Biology

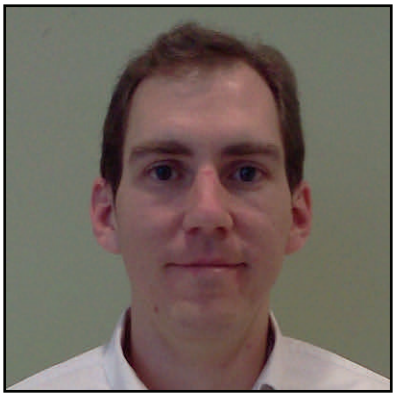
Research Interests

My research interests include autologous, allogeneic, and (GE animal) xenogeneic cell, tissue and organ transplantation, with a particular interest in adult stem cell therapies and Regenerative Medicine Combination Products. These interests were developed during my Ph.D. in transplant immunology, a multi-disciplinary Training Program in Regenerative Medicine, and 5+ years in private and international public Companies in the Regenerative Medicine space, from adult stem cell, islet and organ transplantation, to tissue engineering and medical devices. At the FDA, I hope to utilize my expertise in policy and review activities, and leveraging resources to promote, and contribute to, FDA regulatory science.

Commissioner's Fellowship Project Overview

Advancing Regulatory Science and Innovation in Stem Cells and Regenerative Medicine

Stem cell (SC) therapy, and Regenerative Medicine Combination Products that contain stem cells, are promising treatments for diseases and other conditions with unmet clinical need. Identification and correlation of trends and scientific gap analyses of adult multipotent Mesenchymal Stromal Cell (MSC) product characterizations (including biomarkers), and of other stem cell types from different sources, will contribute to understanding the current state-of-the-industry, and the major gaps in the field. These activities will be mentored by experts in CBER OCTGT, and will involve: i) review of SC INDs/IDEs/510(k)s and database generation, ii) primary literature, and iii) CBER research (i.e. MSC Consortium at NIH). This provides a scientific data-driven groundwork for recommendations and next-steps for how these gaps may be addressed via regulatory science to predict, and assure, the safety and efficacy (quality and potency) of stem cell-based products, such as: i) regulatory science review articles, ii) regulatory policy and standards development, iii) guidance for Sponsors, and iv) potential leveraging of resources from within FDA and outside stakeholders.



Clark Meyer, Ph.D.

Center for Devices and Radiological Health (CDRH)

Preceptor: Nandini Duraiswamy, Ph.D.

Scientific and Professional Background

2011	Post-doctoral researcher, Biomedical Engineering, Texas A&M University
2009-2010	Whitaker Scholar, Biomechanics, IRPHE, Centre National de la Recherche Scientifique (CNRS), UMR 6594, Marseille, France
2009	Ph.D. Biomedical Engineering, Texas A&M University
2003	Ethicon
2002	B.S. Biomedical Engineering, Texas A&M University

Research Interests

I am interested in computational modeling of medical devices, specifically device-tissue interactions, vascular biomechanics, and remodeling. My background is primarily in computational solid mechanics of soft tissue using finite element analysis. I also have experience in experimental fluid mechanics (PIV) and experimental solid mechanics (tissue property characterization, stereoscopic observation of strains). My previous research was particularly focused on varied aspects of abdominal aortic aneurysms (AAA).

Commissioner's Fellowship Project Overview

Computational modeling of device, tissue, and device-tissue interaction for device evaluation

The detailed device-tissue interaction behaviors of many medical devices (such as coronary and peripheral vascular stents, atrial septal occluders, biodegradable polymer devices, and tissue heart values) are complex and challenging non-linear problems. Computational modeling of these cases can provide a means to predict device efficacy and assess likely fatigue life as well as identify potential failure modes. The models generated are also a means to consider a wide variety of use and treatment conditions. From the variations in the results, one can see the relative importance of that variation. Understanding the relative importance and influence of different device design/selection can guide the development of appropriate standards, instructions for use, and test methods. My project looks at the stresses and strains produced by device-tissue interaction for a specific condition-device combination. The project uses patient specific models of the anatomical geometry as well as imaging-based reconstructions of deployed devices to address issues surrounding appropriate device usage, selection, and evaluation.

Jeremiah Momper, Pharm.D., Ph.D.

Center for Drug Evaluation and Research (CDER)
Office of Clinical Pharmacology

Preceptor: Gilbert Burckart, Pharm.D.

Scientific and Professional Background

2006 – 2011	Clinical pharmacist, University of Pittsburgh Medical Center
2011	Ph.D., Pharmaceutical Sciences, University of Pittsburgh
2006	Pharm.D., University of Pittsburgh

Research Interests

Clinical pharmacokinetics and pharmacodynamics; population pharmacokinetics; pharmacogenomics of drug metabolizing enzymes and transporters; pediatric drug development.

Commissioners Fellowship Project Overview

Developmental Effects on Warfarin Pharmacogenomics in Young Pediatric Patients

Genetic factors are important determinants of intra-individual variability in drug disposition and response. In children, the interpretation of a pharmacogenetic effect may be complicated by the development and maturation of metabolic enzymes, transporters, and/or drug targets. This is particularly true when the ontogeny of a component of drug response is unknown, or when multiple independent systems are involved. Therefore, the current project is designed to elucidate the competing effects of pharmacogenetics and ontogeny in children. Warfarin is an oral anticoagulant used for the prevention of thromboembolic events in children with heart disease, atrial fibrillation, and thromboembolic disease. CYP2C9 is a polymorphically expressed enzyme involved in warfarin metabolism, and variant alleles (*CYP2C9*2* and **3*) result in reduced clearance. This reduction leads to an increase in the anticoagulant effect and a decrease in the dose required to maintain the INR within the therapeutic range. Additionally, mutations in the gene that encodes the vitamin K epoxide reductase enzyme complex (VKORC) lead to warfarin resistance and increased dose requirements. Collectively, *CYP2C9* and *VKORC1* genotypes account for nearly 50% of the variability in warfarin dose requirements in adults. This project will evaluate the impact of *CYP2C9* and *VKORC1* gene variants on warfarin dose requirements in children across the pediatric age continuum. Ultimately, a dosing algorithm will be constructed, allowing for the integration of pharmacogenomic advances into pediatric care.

Anh Nguyen, M.D., MBA

Center for Device Evaluation and Radiological Health (CDRH)
Office of Device Evaluation (ODE)

Preceptor: Markham Luke, M.D., Ph.D.

Scientific and Professional Background

- FDA Commissioner's Fellow — 2011-present
- University of Chicago - Booth School of Business — 2009-2011
  Masters Business Administration, Concentration in Finance
- University of Chicago - School of Social Service Administration — 2009-2011
  Graduate Program in Health Administration & Policy
- Adventist Health Systems Midwest – Hinsdale Hospital — 2004-2011
  Division Head of Pediatric Anesthesia, Cardiac Anesthesiologist
- Harvard Medical School – MGH & Children's Hospital Boston — 2003-2003
  Fellowship in Cardiovascular Anesthesia
- Harvard Medical School - Massachusetts General Hospital — 2000-2003
  Residency in Anesthesia
- New Jersey Medical School – University Hospital — 1999-2000
  Internship in General Internal Medicine
- UMDNJ – New Jersey Medical School — 1992-1999
  7-year Honors Combined B.S./M.D. Program

Research Interests

My background is work in healthcare administration, policy, and clinical medicine. My research interests involve the design, development, and implementation of medical devices used in surgery, critical care, and chronic disease management.

Commissioner's Fellowship Project Overview

Guidance Development for Future Medical Devices

FDA has an integral role in identifying and structuring the pathway of future healthcare technologies, to both protect and promote public health. My experience as both a medical officer and as a Commissioner's fellow at FDA has focused on product development, within the pre-market medical devices arena. This has been an invaluable opportunity to obtain multiple proficiencies:

1. Writing Guidance Policies for future medical device design
2. Medical Device Review for Pre-IDE, IDE, 510(k), PMA, and HDE applications
3. Clinical consultation between FDA Centers – CDER and CBER
4. Primary Investigator as part of the FDA Critical Path Initiative

Similar to other parts of the Agency, the Center for Devices and Radiological Health (CDRH) is a collaborative environment between multiple disciplines that serves as the nexus between clinical medicine, basic science, policy, and technology. CDRH protects the health of the public by assuring the safety and effectiveness of medical devices and the safety of radiological products marketed in the United States. To further safeguard the public health, CDRH monitors medical devices and radiological products while in use for continued safety and disseminates accurate, science-based information about the regulated products. The work of Center promotes technologies that improve public health, while constantly adapting to the many changes within healthcare. Similar to the consumer technology industry, medical devices have a shorter development life cycle. Thus, there is a high-level of rapid innovation in the device pre-market space. The opportunity to be part of an organization that facilitates the evolution of healthcare products and services is both a privilege and an immense responsibility.

Li Pang, M.D.

National Center for Toxicological Research (NCTR)

Preceptor: Beverly Lyn‐Cook, Ph.D.

Scientific and Professional Background

Assistant professor	Univ. of Arkansas for Medical Sciences, 2011
Research Instructor	Univ. of Arkansas for Medical Sciences, 2005‐2010
Senior Research Associate	Univ. of Texas Medical Branch at Galveston, 2004-2005
Post‐doctoral Research Associate	Montreal Heart Institute, Canada, 2000-2004
Visiting Scholar	University of Montreal, Canada, 1998-2000
Fellow in Endocrinology	Peking Union Medical College Hospital, China, 1996-1998
M.Sc.	Peking Union Medical College, China, 1996
M.D.	North China Coal Medical College, China, 1993

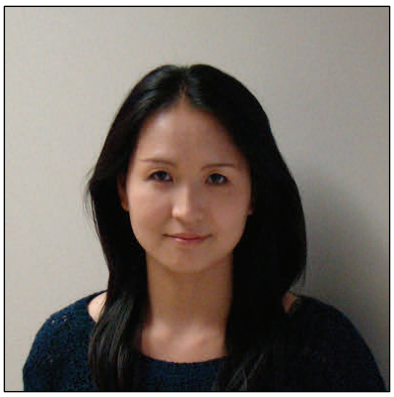
Research Interests

- SiRNA/miRNA-based gene therapy
- Pharmacogenomics and personalized medicine
- Transcriptional and post-transcriptional regulation of ion channels and drug transporters in cancer and cardiovascular disease

Commissioner's Fellowship Project Overview

The Role of ABC-Drug Transporters in Chemoresistance in Pancreatic Cancer: Assessing Drug Safety and Efficacy

Pancreatic cancer is one of the deadliest malignancies with very poor prognosis. Because of no symptoms or nonspecific and varied symptoms, pancreatic cancer is often not diagnosed until it is advanced. Chemotherapy is the main treatment, but due to chemoresistance, the efficacy of chemotherapy is limited. Of the many different, unrelated mechanisms, I am particularly interested in abnormal expression of ATP-binding cassette (ABC) transporters, as the multidrug efflux pumps play an important role in the uptake and distribution of therapeutic drugs. My project is aimed to determine whether abnormal expression of ABC transporters in pancreatic adenocarcinoma contributes to chemoresistance and is associated with the prognosis of the disease. Understanding the molecular mechanisms involved in drug resistance is applicable to the overall mission of FDA in advancing the public health. The results of this study will aid in the future practice of utilizing personalized medicine to make pancreatic cancer chemotherapy more effective and safer.



Ji-Young Park, Ph.D.

Office of Regulatory Affairs (ORA)
Jefferson, AR

Preceptor: Sean W. Linder, Ph.D.

Scientific and Professional Background

2008-2011	Post-Doctoral Associate, Radiation Oncology, Duke University, NC
2006-2008	Post-Doctoral Associate, School of Pharmacy, University of North Carolina at Chapel Hill , NC
2005-2006	Post-Doctoral Associate, Chemistry, University of North Carolina at Chapel Hill, NC
2005	Ph.D. Chemical Engineering, Yonsei University, Korea
1999	M.S. Chemical Engineering, Yonsei University, Korea
1996	B.S. Chemical Engineering, University of Seoul, Korea

Research Interests

My current research interests are the development and discovery of a drug/gene delivery system using liposomal nanoparticles for cancer therapy. These interests include: 1) formulation of liposomal nanoparticles composed of lipids and siRNA, which due to their size are able to cross the blood brain barrier (BBB), and 2) development of novel thermosensitive liposomes containing anticancer pharmaceuticals, MRI contrast agents, DNA/siRNA, proteins, and/or peptides 3) design of targeted liposomal drugs with site-specific affinity. My ultimate goals are to improve current drug delivery system (DDS) in terms of drug transport and drug release in tumor, and to design DDS that enhances efficacy of drug against tumors, and to study physicochemical properties that affect DDS in physiological environment.

Commissioner's Fellowship Project Overview

Development methodologies for the characterization of FDA regulated liposomal products.

Nanotechnology is the control and manipulation of materials with one size dimension (length or width) between approximately 1 – 100 nm. This technology is an emerging science, which is now being utilized within multiple product classifications regulated by the FDA. One key utilization of nanotechnology is the creation of liposomal products. Liposomes are generally defined as engineered vesicles which are composed of a lipid based bilayer. These vesicles are used as a delivery carrier for various therapeutic agents (i.e. pharmaceutical and dietary supplements). The Office of Regulatory Affairs (ORA) currently lacks validated methods for the characterization of the physico-chemical properties of commercially available liposomal products. Our project will focus on bridging this knowledge gap to ensure that we are able to fulfill our mission of protecting and promoting public health through regulatory science.

Katya Petrova, Ph.D.

National Center for Toxicological Research (NCTR)

Preceptor: Laura Schnackenberg, Ph.D.

Scientific and Professional Background

2004-2011	Postdoctoral Research Associate, Vanderbilt University
2003-2004	Assistant Professor, Sofia University, Bulgaria
2000-2003	Senior Expert, Executive Environmental Agency, Sofia, Bulgaria
1992-1995	Research Assistant, Bulgarian Academy of Sciences, Institute of Organic Chemistry, Sofia, Bulgaria
2004	Ph.D. in Technology of Fine Organic Synthesis and Biochemical Synthesis, Sofia University, Bulgaria
1992	M.S. in Chemistry and Physics, Sofia University, Bulgaria

Research Interests

Over the years, I have acquired extensive research experience in chemical toxicology, environmental analytical chemistry and organic synthesis of potential target molecules for medical applications. As a postdoctoral fellow, I have had the opportunity to work on several projects focused on DNA adducts arising from reactive oxygen species and from their reactions with lipids. The use of various modern mass spectrometry and NMR techniques has been an integral part of my research. During my postdoctoral fellowship at Vanderbilt University, I developed an interest in the mechanism by which modified nucleosides are generated and the re-arrangements of DNA adducts. These mechanistic studies involved trapping and analysis of intermediates, using both chemical and spectroscopic methods.

Commissioner's Fellowship Project Overview

Development and Application of LC-SPE-NMR Methods to Evaluate Biomarkers of Hepatotoxicity

Hepatotoxicity is a common complication in drug development and one of the main reasons for withdrawal of FDA-approved drugs from the market. The most common used biomarkers for hepatotoxicity, alanine aminotransferase (ALT) and aspartate aminotransferase (AST), are good markers of damage but are not always elevated. More specific biomarkers of liver injury may benefit public health by removing suspect compound earlier in the development process. Biomarkers are also needed that can predict potential liver damage and indicate recovery after a toxic insult. The objective of this study is to develop a metabolomic approach to identify more specific biomarkers of hepatotoxicity in liver tissue and biofluids from rats exposed to well-known hepatotoxicants. LC-NMR-based methods will be developed for detection of targeted metabolites suspected to be altered following a hepatotoxic insult in liver tissue from rats exposed to acetaminophen, which is commonly used analgesic drug and carbon tetrachloride, which is used as an industrial compound. Both compounds are known to induce liver injury and this study aims to prove that the observed biomarkers are the result of liver necrosis caused by these known hepatotoxicants. The expectation is that the identified metabolites can be translated to humans and provide better prediction and identification of liver damage due to exposure (inadvertent or chronic) to hepatotoxic xenobiotics.

Prakash Rath, Ph.D.

Center for Biologics Evaluation and Research (CBER)

Preceptor: Anita Richardson, M.A.S.

Scientific and Professional Background

2010-2011	Postdoctoral Fellowship, Neurology, Johns Hopkins School of Medicine and Kennedy Krieger Research Institute
2009	Ph.D. Biological Sciences, University of Missouri - Columbia
2004	M.S. Cell and Molecular Biology, University of Arkansas - Fayetteville
2002	B.S. Zoology, University of Arkansas - Fayetteville

Research Interests

My interests are focused on the decision making processes at the forefront of translational research for advancing cellular-based therapies and product development, i.e., the regulatory aspects involved in transitioning bench discoveries to the clinical setting. During my Ph.D. studies I identified and characterized brain tumor stem/initiating cells using next-generation epigenetic and genetic technologies, and my postdoctoral studies involved investigating the anti-tumor effects of tyrosine kinase inhibitor therapies that target glioma stem/initiating cells *in vivo*. The Commissioners Fellowship Program provides an opportunity to learn about FDA's guiding principles and regulatory science policies surrounding biologics, and more importantly the regulation of translational science with respect to compliance and fulfilling FDA's mission of protecting the public health.

Commissioner's Fellowship Project Overview

Science Policy and Compliance Program Risk-Modeling Related to the Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

Ensuring that manufacturers comply with food and drug laws is an essential role of the Agency, and the premise of this regulatory project. This project is designed to assist the Office of Compliance and Biologics Quality (OCBQ) in their role of ensuring the quality of human cells, tissues and cellular and tissue based products (HCT/Ps) that have unique regulations promulgated under section 361 of the Public Health Service Act (referred to as Section 361 HCT/Ps). The overall goal of this project is to increase the safety of Section 361 HCT/Ps by creating a guidance document and risk-based compliance tool to help prevent the introduction, transmission, and spread of communicable disease transmission, which are consistent with developing the Agency's regulatory science programs. The first part of this project will be to create a guidance document for industry that addresses reporting procedures for biological product deviations (errors and accidents in manufacturing, donor testing, facilities, etc.) for Section 361 HCT/Ps. Examples of Section 361 HCT/Ps include bone, ligaments, skin, dura mater, hematopoietic stem/progenitor cells, oocytes, and embryos that are minimally manipulated and intended for homologous use, amongst additional criteria. The other portion of this project will be to create a risk-based assessment tool to assist with prioritizing inspections of registered establishments that manufacture Section 361 HCT/Ps. This tool will analyze the vast amounts of information OCBQ receives every year such as inspection reports, summaries, recalls, adverse reaction reports, deviation reports, complaints, etc., to come up with a risk ranking for establishments. This ranking will be utilized to direct the best use of OCBQ's inspectional resources to high-risk establishments that will likely yield the greatest public health impact.

Subrat N. Rout, Ph.D.

Office of Regulatory Affairs
San Francisco District Office
Alameda, CA

Preceptor: Gary Hartman, B.S, M.A.

Scientific and Professional Background

2009-2011	Postdoctoral Fellow, Center for Advance Drug Research, SRI International, Harrisonburg, VA
2008-2007	Postdoctoral Fellow, University of Maryland, College Park
2002-2007	PhD, Virology, University of Maryland, College Park
1999-2001	MVSc, Animal Biotechnology, Indian Veterinary Research Institute, India
1992-1998	BVSc & AH, Orissa University of Agriculture & Technology, India

Research Interests

I obtained my Master degree and Ph.D. in the field of virology. During my post doctoral training I have worked on small molecule screening for potential target against Dengue virus. Some of my previous work has involved studying molecular basis of pathogenesis, reverse genetics of negative strand RNA viruses and screening of small molecule against RNA viruses. My current research interest includes developing detection method for enteric viruses causing food borne illness and learning regulatory aspects at FDA.

Commissioner's Fellowship Project Overview

Development of a liquid mid-density micro array assay for the detection of food-borne enteric viruses using Luminex® xMAPTM technology

Hepatitis E is a liver disease caused by the Hepatitis E virus (HEV). HEV infection is widespread in the developing world and usually results in a self-limited, acute illness. In the current climate of globalization, food borne hepatitis E outbreak can occur due to importation of contaminated food from endemic countries. Title II of the 2011 Food Safeties and Modernization Act (FSMA) outlines the FDA's commitment to reduce food safety threats by redirecting the agency's focus from one of the response to one of the prevention. By detecting the HEV in food samples at an early stage, the number of food-borne outbreaks can be minimized. We are developing a RT-PCR based assay to detect HEV genome from food samples and use it to develop a liquid mid-density microarray assay using Luminex® xMAP™ technology. However, development of this new assay needs to be validated before the implementation in reference laboratories. Furthermore, our aim is to combine this assay method with other Luminex® xMAP™ based assays to develop a multiplex assay that can detect Norovirus and Hepatitis A Virus and HEV in a single tube from food samples.

Kristin Schultz-Kuszak, Ph.D.

Center for Biologic Evaluation and Research (CBER)

Preceptor: Michail Alterman, Ph.D.

Scientific and Professional Background

2009-2011	IRTA Postdoctoral Research Fellow at the National Institute on Drug Abuse
2009 PhD	Analytical Chemistry, University of Michigan
2005 MS	University of Michigan
2003 BA	Lawrence University

Research Interests

My research interests lie in the development and application of analytical chemistry and biochemical methods to elucidate physiological and pathological pathways relevant for public health. As an analytical chemist I always enjoy the challenge of looking for the proverbial needle in the haystack. In my graduate and postgraduate work I studied two different neurochemical systems: the interactions between dopaminergic and estrogen signaling that promote susceptibility to drug addiction and the opioid signaling networks which induce withdrawal symptoms. Both pursuits utilized in vivo microdialysis coupled to capillary electrophoresis or HPLC. Working at the National Institute on Drug Abuse solidified my interest in doing research that directly benefits public health. I look forward to learning more about regulatory science in the Commissioner's fellowship program as well as expanding my skill set to include protein analysis and mass spectrometry.

Commissioner's Fellowship Project Overview

Proteomic Characterization of Multipotent Stromal Cells Seeded on Different Scaffolds to Uncover Osteogenic Differentiation Biomarkers

Multipotent stromal cells (MSCs) have garnered a lot of attention in the field of regenerative medicine due to their low immunogenicity and immunomodulatory properties. MSCs are effective treatments in animal models of a variety of ailments including cardiac, spinal, and bone trauma. Spurred by these promising preclinical results, a number of IND applications have been filed with CBER. Acquiring FDA approval of these new therapies is complex because there are few historical characterization assays to work with. These challenges prompted the formation of a research consortium within OCTGT whose goal is to develop a quantitative and qualitative assay to systemically identify biomarkers which will predict the *in vivo* performance of transplanted MSCs. As part of this consortium, my research project is to analyze the proteome of MSCs cultured under conditions that promote osteogenic differentiation to uncover specific biomarkers indicative of osteoblast development. I will compare the MSC proteome of cells cultured with osteogenic chemical supplements on a flat surface to MSCs cultured on a 3D polymeric scaffold that induces osteogenic differentiation. Both Electrospray and Matrix Assisted Laser Desorption Ionization mass spectrometry methods will be utilized to characterize the MSC differentiation proteome.

Jalal Sheikh, Ph.D.

Division of Cell and Gene Therapy
Office of Cellular, Tissue, and Gene Therapy
Center for Biologics Evaluation and Research (CBER)

Preceptor: Kimberly Benton, Ph.D.

Scientific and Professional Background

- M. Sc in Molecular Biology (1995): Institute of Molecular Biology and Biotechnology, Free University of Brussels (VUB), Belgium.
- PhD in Molecular microbiology (1999): Faculty of Science, VUB, Belgium.
- Post-doctoral Fellowship (1999-2004): Center for Vaccine Development, University of Maryland, Baltimore (UMB), Maryland.
- Faculty member (2004-2008): School of Medicine, UMB, Baltimore, Maryland.
- Senior Microbiologist (2008-2010): Baxter Bioscience Inc.
- International QA/QC Coordinator (2011): Johns Hopkins University, Baltimore, Maryland.

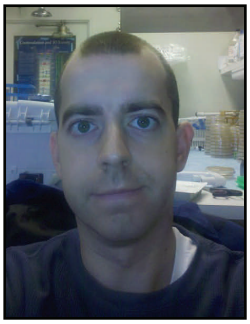
Research Interests

I am a clinical microbiologist and molecular biologist by training, education and experience and have been working in various microbiology disciplines. I worked for the clinical laboratories where I was involved in all stages of testing biological specimens including sample processing to releasing results for patients care. I did my post-doctoral training on bacterial pathogenesis research and molecular diagnostics at the Center for Vaccine Development (CVD) at the University of Maryland, Baltimore. I joined in a Vaccine Manufacturing Plant of Baxter Bioscience Inc as a senior microbiologist in its QC/QA microbiology department and served for two years until the plant moved to overseas. Later, I joined in the Department of Pathology at Johns Hopkins University, Baltimore as an International QA/QC Quality Coordinator for Clinical laboratories where the group oversees and monitoring the quality system of about 170 clinical labs worldwide by following GCLP and CLSI/CLIA regulations. During my tenure in pharmaceutical industry and in the quality systems, I came across lots of federal and international regulations. I am fascinated with FDA's regulations which ensure the best products and ethical services for the public health within the US and overseas by ensuring the safety, accuracy and efficacy. I would like to invest my experience in the translational research which will provide benefit for the public health of the US and overseas. FDA is an ideal place which harmonizes the application of translational research guided by ethical regulations and ensures the protection of public health of the American community. The FDA Commissioner's Fellowship training will provide a unique opportunity to learn more about FDA rules and regulations; in-depth understanding of the science behind regulatory reviews and provides a unique opportunity to complete research projects of important public health issues.

Commissioner's Fellowship Project Overview

Rapid Microbiological Methods (RMM) for Sterility Testing of Cellular and Gene Therapy Products

Sterility is a common aspect of ensuring the safety of Biological Products. FDA regulations require that the sterility of each lot of each product, with the exception of certain products, be demonstrated by the performance of prescribed sterility tests. Manufacturers of innovative products, such as cell and gene therapy products, as well as manufacturers of currently approved products, may benefit from sterility test methods with rapid and advanced detection capabilities. Most cell and gene therapy products are administered to patients before results from standard 14 day sterility tests (required by 21 Code of Federal Regulations 610.12) are available. The CFR method relies on manually inspecting at defined intervals whether bacterial culture media that has been inoculated with product appears contaminated. Instruments developed by industry have automated the reading of sterility cultures, potentially allowing for more sensitive and rapid methods of product contamination, and with less operator intervention. Some examples of novel methods with the potential to detect viable microorganisms include the Adenosine Triphosphate (ATP) bioluminescence, chemiluminescence, and carbon dioxide head space measurement. Under the regulations sponsors are allowed to use such alternate methods for sterility determination, however, they must demonstrate equivalency of the alternate method with the CFR method. Unfortunately, no comprehensive comparison of these rapid microbiological methods (RMMs) exists.



Jonathan Swoboda, Ph.D.

Center for Biologic Evaluation and Research (CBER)

Preceptor: Karen Elkins, Ph.D.

Scientific and Professional Background

- B. Sc. with honors from Brown University, Biochemistry, Providence Rhode Island (1999-2003)
- MA from Harvard University, Chemical Biology, Cambridge, Massachusetts (2004-2005)
- Ph.D. from Harvard University, Chemical Biology, Cambridge, Massachusetts (2004-2009)
- Post-doctoral experience from The Scripps Research Institute, Chemical Biology, La Jolla, California (2009-2011)

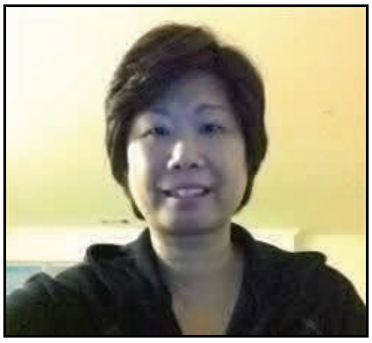
Research Interests

My research interest is in the field of drug discovery within the areas of infectious disease and regenerative medicine. For my Ph.D. and post-doctoral training, I focused on high-throughput screening to identify novel compounds targeting *S. aureus* and to induce proliferation in terminally differentiated cells for cell-based therapies. I am currently working as a Commissioner's Fellow in the lab of Dr. Karen Elkins in CBER. My project focuses on understanding host-pathogen interactions for *F. tularensis*.

Commissioner's Fellowship Project Overview

The biological role of the cytokine p40 in clearing chronic infections caused by vaccination with Francisella tularensis Live Vaccine Strain (LVS)

Previously, the Elkins lab has shown that mice deficient in the p40 subunit of IL-12 exhibit a chronic infection when vaccinated with the Live Vaccine Strain (LVS) of the intracellular bacterium *Francisella tularensis*, while the wild type control mice completely clear the vaccinating infection. This defect cannot be readily attributed to the functions of p40 as part of either IL-12 or IL-23 heterodimers. The p40 protein is also produced and secreted *in vivo* in relatively large amounts as a homodimer ($p40_2$), which can block the binding of IL-12 (p70) to its receptor, but the *in vivo* function of the homodimer form remains elusive. We are therefore interested in evaluating novel biological roles the p40 subunit plays during vaccination with this live attenuated bacterial strain, including clearance. Using a combination of tissue sectioning and flow cytometry with isolated cells, we will examine the localization and expression of p40 in LVS-infected EYFP p40 transgenic mice over time; in these mice, cells (notably DCs and macrophages) that produce p40 can be detected by expression of YFP. Similarly, to determine unique sites of p40 expression, relative p40 gene expression in selected tissues and cells (as directed by results of p40 protein expression using transgenic mice) will be determined and compared to the relative expression of the p35 chain of IL-12 and the p19 chain of IL-23. Because T lymphocyte function is critical to clearance of *Francisella*, the relative T cell function of lymphocytes from spleens, livers, and lungs of LVS-immune WT, p40 KO, and p35 KO mice will be compared. Further, LVS-immune cells restimulated by *in vitro* co-culture with LVS-infected macrophages will be recovered and compared for relative expression of a large panel of immunologically-related genes by qRT-PCR. Experience to date indicates that chronic LVS infection in p40 KO mice drives continued production of many pro-inflammatory cytokines, and presumably activation-related molecules; therefore we expect many entities will be upregulated in cells from LVS-infected p40 KO mice compared to cells from LVS-infected WT mice. Taken together, this work will provide a better understanding of the biological role of p40 during *in vivo* clearance of infections with intracellular bacteria and successful vaccination with live attenuated vaccine strains, as exemplified by *F. tularensis* LVS.



Wendy Tan, Ph.D.

Center for Biologics Evaluation and Research (CBER)

Preceptor: Marian Major, Ph.D.

Scientific and Professional Background

2007-2011 Postdoctoral Research Fellow, Emory Vaccine Center, Emory University
2006-2007 Postdoctoral Research Fellow, Centers for Disease Prevention and Control
2001-2006 Ph.D. Biological Sciences (Virology), Western Michigan University
1998-2001 B.Sc. Biomedical Sciences, Western Michigan University

Research Interests

My research interests are in the areas of cellular immunity induced during vaccinations or exposure to pathogens. Primarily, I use FACS (Fluorescence-activated Cell Sorting) to characterize the antigen-specific T cell populations during immune induction to assess their phenotypic and functional characteristics and whether they become long-lived memory cells to confer future protection against re-infection by the same pathogen or intended pathogen, in the case of vaccination. I am especially excited to be able to expand my experience and interests in the capacity of a Commissioner's Fellow to conduct research and review work in vaccines that are sorely needed to eradicate some chronic diseases that have not yet any vaccines available.

Commissioner's Fellowship Project Overview

Improvement of hepatitis C virus (HCV) vaccines through phenotypic T-cell analysis and potency assay development

HCV infection is one of the many chronic diseases for which there is no effective prophylactic vaccine available. The goal of my project is to identify and characterize HCV antigen-specific T cells to understand the phenotypes and functional quality of these T cells following vaccination with recombinant vaccines. A secondary goal of the project is to develop a FACS-based potency assay to show consistent immunogenicity of T-cell-targeting vaccines for clinical trial production and long term manufacturing. Together, these results will impart valuable knowledge about the different T cell phenotypes induced by different vectors and provide valuable guidance for future vaccine development. The FACS-based assay will enable consistent determination of the potency of each vaccine from lot-to-lot during mass production to ensure public safety. This knowledge will provide fundamental and essential information for regulatory reviews of T-cell based vaccine applications.

Jacquline AM Yancy, Ph.D.

Center for Devices and Radiological Health (CDRH)
Office of In Vitro Diagnostic Device Evaluation and Safety

Preceptors: Elizabeth Mansfield, Ph.D. and Katherine Serrano, B.S.

Scientific and Professional Background
Sr. Scientist, Research and Development, Canon US Life Sciences, 2007-2011
Post Doctoral Scientist- Canon US Life Sciences, Rockville, MD, 2006-2007
Ph.D. in Microbiology, Molecular Biology concentration, Howard University, 2006
B.S. in Biology, Virginia Union University, 2001

Research Interests
I have had an interest in health disparities among minority groups. My doctoral research involved investigating matrix proteins and their involvement in metastasis of breast cancer in African American and Caucasian women. During my post-doctoral fellowship, I participated in a validation project with Canon US Life Sciences, the Department of Homeland Security, University of Maryland at College Park, and The Institute for Genomic Research on validating a new bioinformatics pipeline of microbial genomes to ascertain the sensitivity and specificity in differentiating between species of bacteria particularly agents of health consequences. My current interests are in understanding the regulatory policies related to in vitro diagnostics and medical device development.

Commissioner's Fellowship Project Overview
Development of guidance for Direct-to-Consumer (DTC) genetic testing: A Rapid and Systematic approach for determining the clinical significance and validity of adding new intended uses to already approved/cleared DTC genetic tests.

Currently, Direct to Consumer genetic testing (DTC) is an area of regulatory concern to FDA. DTC genetic tests are tests offered directly to consumers (most of whom are healthy) without a doctor's prescription, and generally encompass multiple tests and interpretations for genetic variations. Most of the genetic variations that are reported have clinical implications. This model has created much discussion around public health and other social/legal/ethical concerns. The primary goal of my project is to develop recommendations for determining when new scientific information can reasonably support additional DTC test offerings together with an already approved test system.

Xiaoxia Yang, Ph.D.

National Center for Toxicological Research (NCTR)

Preceptor: Jeffrey Fisher, Ph.D.

Scientific and Professional Background

2009 - 2011	Research Associate/Scientist, The Ohio State University
2006 - 2009	Postdoctoral Fellow, Kansas University Medical Center
2007	Ph.D.	Pharmaceutics, National University of Singapore, Singapore
2002	M.S.	Pharmaceutical Analysis, National Institute for Food and Drug Control, China
1999	B.S.	Pharmacy, West China University of Medical Sciences, China

Research Interests

Through my educational and professional experience, I have acquired in-depth knowledge in pre-clinical and clinical pharmacokinetics and pharmacodynamics. I have worked on drug metabolism, drug transport, drug-drug interaction and pharmacokinetic modeling. My current research interests involve the development and use of physiologically based pharmacokinetic models to understand key factors contributing to Bisphenol A dosimetry.

Commissioner's Fellowship Project Overview

Pharmacokinetic modeling: prediction and evaluation of route dependent dosimetry of bisphenol A in rats at different development stages

Pharmacokinetics of bisphenol A (BPA) has been characterized in laboratory animals and humans. To facilitate the extrapolation of animal toxicity findings to humans and assist the interpretation of human BPA biomonitoring, the quantitative comparison of BPA dosimetry between animals and humans is warranted. My project is to develop a suite of physiologically based pharmacokinetic models (PBPK) to predict internal doses for both aglycone and conjugated forms of BPA in rats at different reproductive stages. These models will be used for the 90-day and 2-year National Testing Program toxicity studies with BPA at NCTR. The accomplishment of this project can be directly related to the control of public health risks posed by BPA, and help provide critical information for FDA to make science based regulatory decisions regarding the use of BPA.

Diana M. Yoon, Ph.D.

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

Preceptors: Jiyoung M. Dang, Ph.D., Mark H. Lee, Ph.D., and Elias Mallis, B.S.

Scientific and Professional Background

2009-2011	Postdoctoral Research Fellow, Rice University
2003-2008	Ph.D. Chemical Engineering, University of Maryland
1999-2003	B.S. Biomedical Engineering and B.S. Chemical Engineering, Carnegie Mellon University

Research Interests

My area of expertise is in the field of tissue engineering with a concentration in orthopedic tissues. My Ph.D. research focused on tissue engineering strategies for cartilage, more specifically investigating the effect of construct properties, such as cell to cell contacts, biomaterials, matrices, and proteins, on chondrocyte gene expression. My postdoctoral research investigated the mechanical properties of synthetic polymers for potential application in load bearing bone defects as well as controlling the delivery of growth factors to aid in bone regeneration.

Commissioner's Fellowship Project Overview

Opportunities and challenges of using standards for premarket review of bone regenerative medicine products at CBER and CDRH

The field of tissue engineering/regenerative medicine (TE/RM) is providing the biomedical community with innovative treatment options to meet unmet needs across a wide range of clinical indications. For bone replacement and regeneration, a variety of TE/RM approaches are currently used, including biologics, devices, tissues, drugs and combination products. TE/RM products are evaluated under established regulatory pathways at the FDA. Factors such as the composition, understanding of mechanism of action and intended use of the product are considered in determining whether bone healing TE/RM products are reviewed primarily at CBER, CDER or CDRH. Standards developed by Standard Developing Organizations (SDOs) such as American Society of Testing and Materials (ASTM), International Organization for Standardization (ISO) and United States Pharmacopeial Convention (USP) facilitate evaluation of these products. For example when focusing on non-clinical studies, standards can provide knowledge that is beneficial in assay development, manufacturing process, and animal studies). As standards typically are written to address a general or specific purpose and the content can be definitive or broad, identification of pertinent information for a specific application is important. Therefore, the goal of this project is to determine how standards can be most effectively utilized to aid in the evaluation of non-clinical aspects of bone TE/RM products at CBER and CDRH.

Shifu Zhao, Ph.D.

Office of the Commissioner (OC)

Preceptor: Vicki Seyfert-Margolis, Ph.D.

Scientific & Professional Background

2006-2011	Sr. Clinical Data Manager, Allergan
2004-2006	Manager, Clinical Data Operations, Touchstone Research
2002-2004	Clinical Data Manager, Nabi Biopharmaceuticals
2001-2002	Data Validation Programmer, Cato Research
2000-2001	SAS Programmer Analyst, Westat
1988-1994	Plant Protection, Quarantine and Pesticide Agency, Jiangxi, China
2000	Ph.D. Entomology, West Virginia University
1988	M. S. Insect Ecology, Fujian Agricultural University, China
1985	B. S. Plant Protection Science, Jiangxi Agricultural University, China

Research Interests

My early research experience was focused on plant health, involving effective monitoring, forecasting and management of plant epidemics to ensure safe and sustainable food production and minimal impact on the environment. My graduate work focused on eriophyoid mites as special vectors of plant virus diseases and discovered hundreds of mite species new to science.

After receiving my PH.D., I moved into the areas of healthcare and clinical research, specifically protocol design, data management and analysis. Currently my areas of focus are: policies and practices providing for optimal clinical trial efficiency and data quality; innovative trial design, data analysis and review methodologies and tools supporting effective identification of clinical and scientific evidence.

Commissioner's Fellowship Project Overview

The FDA Patient-Centered Outcomes Research (PCOR) promoting personalized medicine

FDA has long seen a critical need in upgrading its capacity in effective and efficient management and analysis of the clinical trial data it receives. The FDA PCOR project directly addresses such a need in two major fronts:

Standardization and integration of legacy submission data: clinical data from selected groups of studies across CBER, CDER and CDRH will be transformed and populated into FDA's centralized study data repository that is currently being built. Such an effort will pave the road to success for FDA's future data conversion tasks as well as new data submissions by sponsors.

PCOR pilot studies using FDA and external data sources: the research efforts are expected to provide answers to important scientific and regulatory questions of interest concerning patient outcomes and trial design strategies. In addition, the collective experience of the FDA PCOR project will help further define data acquisition requirements and best practices relevant to clinical studies in specific therapeutic areas.

FDA Commissioner's Fellowship Program

2011 Preceptors

Michail A. Alterman, Ph.D.

Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research (CBER)
NIH Campus, Bethesda, MD

Background

B.S. – Organic Chemistry, Moscow Lomonosov Institute of Fine Chemical Technology.
M.S. – Bioorganic Chemistry, Moscow Lomonosov Institute of Fine Chemical Technology.
Ph.D. – Biochemistry, Russian State Medical University, Moscow, Russia.
FDA Experience – 5 years

Research Interests

The development and availability of "-omics" technologies has moved analytical research to the forefront of biomedical sciences and it is imperative that promising findings are translated rapidly into new approaches and strategies for product development. Our work reflects that path by developing new state-of-the-art mass spectrometry-based proteomic approach for testing of biological products quality and identity. Biologic products are derived from living sources and represent mixtures of proteins, carbohydrates, lipids and other biomolecules of enormous analytical complexity. The major physical-chemical feature that can be measured for all components of biological mixtures and uniquely identify and distinguish them is molecular mass. Mass spectrometry-based proteomics is the leading technology for the rapid analysis of complex protein mixtures. This technology provides means for concomitant analysis of all components of biological products. The goal of this research program is to develop, evaluate and adapt mass spectrometry-based proteomic techniques for qualitative and quantitative analytical testing of cells, cell-derived products, and vaccines.

Kimberly Benton, Ph.D.

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

Background
Ph.D. – Microbiology
FDA Experience – 10 years

Research Interests
Sterility is a common aspect of ensuring the safety of Biological Products. FDA regulations require that the sterility of each lot of each product, with the exception of certain products, be demonstrated by the performance of prescribed sterility tests. Manufacturers of innovative products, such as cell and gene therapy products, as well as manufacturers of currently approved products, may benefit from sterility test methods with rapid and advanced detection capabilities. Most cell and gene therapy products are administered to patients before results from standard 14 day sterility tests (required by 21 Code of Federal Regulations 610.12) are available. The CFR method relies on manually inspecting at defined intervals whether bacterial culture media that has been inoculated with product appears contaminated. Instruments developed by industry have automated the reading of sterility cultures, potentially allowing for more sensitive and rapid methods of product contamination, and with less operator intervention. Some examples of novel methods with the potential to detect viable microorganisms include the Adenosine Triphosphate (ATP) bioluminescence, chemi- luminescence, and carbon dioxide head space measurement. Under the regulations sponsors are allowed to use such alternate methods for sterility determination, however, they must demonstrate equivalency of the alternate method with the CFR method. Unfortunately, no comprehensive comparison of these rapid microbiological methods (RMMs) exists.

The fellowship position will have a strong regulatory focus and the Fellow will learn and perform regulatory review. The primary project would be to compile and review the existing data for its adequacy to support equivalence between RMMs and the CFR method, and identify any critical gaps in the data. Sources of existing data include the scientific literature and data submitted to individual regulatory applications. The Fellow may also have the opportunity to work in CBER microbiology laboratories and in other areas of CBER relevant to the goals of the project.

Gilbert Burckart, PharmD

Office of Translational Sciences
Office of Clinical Pharmacology
Center for Drug Evaluation and Research (CDER)
Silver Spring, MD

Background
PharmD, Pediatric Clinical Pharmacology
3 years at FDA

Research Interests
My research for the past 10 years has focused on the application of pharmacogenomics to explain the variability in drug response, especially in pediatric patients. More recently, I have explored the applicability of pharmacogenomics to drug safety with immunosuppressive drugs, and have an ongoing study of warfarin pharmacogenomics in pediatric patients recruited at three national children's hospitals. My collaborators include a diverse group of clinical scientists at major medical centers and at the NIH.

O. Alberto Chiesa, D.V.M., M.S., Ph.D.

Office of Research
Division of Animal research
Center for Veterinary Medicine (CVM)
Laurel, MD

Background
D.V.M. — Buenos Aires, Argentina
M. S. — Universidad Autonoma de Barcelona, Spain
Ph. D. — Universidad Autonoma de Barcelona, Spain
FDA experience —10 years

Research Interests
Development of tissue fluid correlations for antimicrobial agents.

Nandini Duraiswamy, Ph.D.

Office of Science & Engineering Laboratories
Division of Solid & Fluid Mechanics
Center for Devices and Radiological Health (CDRH)

Background

Education

Ph.D. in Biomedical Engineering (Dec. 2005), Florida International University (FIU),
MS in Biomedical Engineering (Dec. 2000), Texas A&M University

Professional Experience

Staff Fellow, CDRH/OSEL, - 5/2009 - present
Research Associate, Cardiovascular and Engineering Center, FIU, Miami, FL , 06/2002 – 05/2008
Biomedical Engineer, Micro Systems Engineering, Biotronik, Inc., Portland, OR 08/2000 – 06/2002

Research Interests:

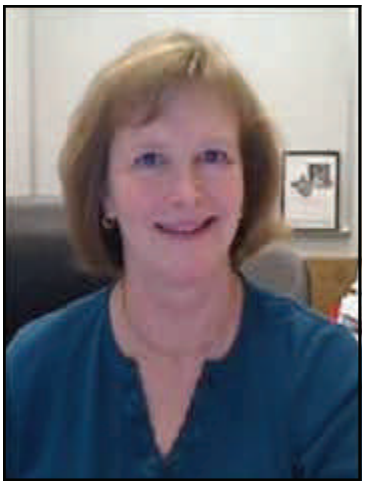
The OSEL/DSFM Solid Mechanics laboratory assists CDRH with issues related to the response of medical device materials and structures to applied stress in both pre-market evaluations and post-market adverse event reports. The materials of interest include traditional engineering materials like metals and polymers, in addition to materials of biological origin and those used in tissue engineered medical products (TEMPs). Common principles of stress analysis can be applied to this broad spectrum of materials. We have the capabilities to measure mechanical properties ranging from the tensile strength of sutures and medical glove materials, to the fatigue strength of total joint prostheses. Besides purely mechanical characterizations, our measurement capabilities for TEMPs constructs and scaffolds include quantification of phenotypic stability and the histomorphology of TEMPs relevant cell types. The combined output of this effort includes improved critical review of manufacturers' claims and data, test method development, material and methods standards and guidance document development, and publications related to the public health impact of medical device materials design, fabrication, or failure. Currently, my main research work focusses on leaflet dynamics with percutaneous heart valves and perforation potential with pacemaker/defibrillator leads

Aref M El-Demerdash, Ph.D.

Kansas City District Laboratory
Office of Regulatory Affairs (ORA)
Lenexa, KS

Background
Years employed with FDA: 2
Ph. D. Environmental toxicology
Texas Southern University
M. Sc. Transportation planning and management
Texas Southern University

Bio/Research Interests
Dr. Aref El-Demerdash obtained his PhD in Environmental Toxicology form Texas Southern University in December, 2001. His Master of Science in Transportation Planning and Management from the Texas Southern University in May, 1994. His B.S. in Engineering/Electronics and Telecommunication from Ain-Shams University, Cairo- Egypt in December, 1990. He is experienced in analytical chemistry research, method development, laboratory operation and maintenance. He serves as a technical authority in providing consultation in the areas of his expertise. Conducts analysis of research data and prepares technical reports and manuscripts for publication and presentation. Also, develops and modifies methods to establish approaches and precedents to develop methods and procedures to apply basic principles and theories to further the agency mission using good scientific principles. Prior to joining the FDA in 2008 he was an Assistant Professor at Texas Southern University where he advised M.S. and PhD students on research in the areas of environmental toxicology, engineering technology and transportation management. He served as a lead member for several environmental research projects sponsored by the National Science Foundation (NSF), Department of Energy (DOE), Environmental Protection Agency (EPA), and the National Aeronautics and Space Administration University Research Center (NASA-URC). Since joining the FDA in 2008 Dr. El-Demerdash has analyzed many samples comprised of complex matrices by chromatography using LC, GC, GC/MSD, and LC/MS/MS and developed and validated methods using this equipment. He has performed independently within established methods and procedure providing training in analytical techniques and programs. He serves as a technical point of contact for methodology and analyses and reviews and evaluated analytical proficiencies of other chemist. Provides training in analytical methods, use and maintenance of equipment, and program requirement.



Karen L. Elkins, Ph.D.

Laboratory of Mycobacterial Diseases and Cellular Immunology
Division of Bacterial, Parasitic, and Allergenic Products
Office of Vaccines Research and Review,
Center for Biological Evaluation and Research (CBER)
NIH Building Bethesda, MD

Background
B.A., Wake Forest University, Winston-Salem, NC, Chemistry
Ph.D., Duke University, Durham, NC., Microbiology and Immunology
Senior investigator / regulatory reviewer, CBER, 1993 - present

Research Interests
The research interests in the Elkins laboratory concern mechanisms of protective immunity to intracellular pathogens, including potential bioterrorism agents. Correspondingly, IND and BLA review work involves vaccine products indicated for prevention of disease caused by intracellular pathogens, including tuberculosis, tularemia, malaria, *Leishmania*, and Q fever (*Coxiella burnetti*). Using mouse models of infection *in vivo*, our research focuses on role of T and B lymphocytes, macrophages, dendritic cells, NK cells, neutrophils, and their products (e.g., antibodies, cytokines, and chemokines), in protective immunity to *Francisella tularensis* and *Mycobacterium tuberculosis*. We are particularly interested in understanding the nature of *in vivo* T cell effector mechanisms that control intramacrophage bacterial growth. The goal of these studies is the derivation of practical correlates that will predict vaccine-induced protection against intracellular bacteria (including functional correlates and biomarkers).

Jeffrey Fisher, Ph.D.

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

Background
Ph.D. – 1987 Miami University (Zoology/Toxicology)
FDA Experience – 1 Year

Research Interests
The development and use of physiologically based pharmacokinetic (PBPK) models and biologically based dose response (BBDR) models for human health risk assessment.

Gary Hartman, MA

San Francisco District Laboratory
Office of Regulatory Affairs (ORA)
Alameda, CA

Background
BS Biology Iowa State University
MA Cell and Molecular Biology, San Francisco State University
FDA Experience - 23 years

Research Interests:
Detection and identification of enteric viruses and bacteria in food matrices.

Sunee Himathongkham, D.V.M., M.P.V.M., Ph.D.

Office of Regulatory Affairs
San Francisco District Laboratory
Alameda, CA

Background
Ph.D. in Comparative Pathology, University of California at Davis.
Master of Preventive Veterinary Medicine, University of California at Davis.
Doctor of Veterinary Medicine, Chulalongkorn University, Thailand.

Government Work Experiences
2 years with FDA
7 years with California Department of Public Health

Research Interests
- Rapid molecular methods for detection and identification of foodborne pathogens.
- Molecular typing methods for microbial source tracking.

Julie Kase, Ph.D.

Office of the Center Director
Center for Food Safety and Applied Nutrition (CFSAN)
College Park, MD

Background
Ph.D. – University of North Carolina, Chapel Hill School of Public Health
B.S. – Biochemistry, University of the Sciences in Philadelphia
FDA Experience – 2 years

Research Interests
Research activities have touched upon environmental microbiology (e.g. transmission of infectious agents in the environment), the microbiocidal efficacy of chemical disinfectants, and often combined epidemiology-based field work with microbiological laboratory research. Interests focused upon bacteria and viruses spread zoonotically (e.g. shigatoxigenic E. coli, Brucella spp., Hepatitis E virus) and potentially through particular food commodities.

Andrew P. Lin, Ph.D.

San Fransisco Lab Branch
San Francisco District Laboratory
Office of Regulatory Affairs (ORA)
Alameda, CA

Background
Ph.D. – Biology
B.A. – Molecular and Cell Biology
FDA Experience – 7 years

Research Interests

- non-O157 Shiga toxin producing *E. coli*
- Detection of Hepatitis A virus
- High throughput 96 well format analysis

Sean W. Linder, Ph.D.

General Chemistry Branch
Arkansas Regional Laboratory (ARL)
Office of Regulatory Affairs (ORA)
Jefferson, AR

Background
Ph.D. – Analytical Chemistry, University of Arkansas
B.S. – Chemistry, Henderson State University
FDA Experience – 2 Years

Research Interests
My current research interests include:
1. Development of Screening Methodologies for the Detection of Nanoscale Silver Using Inductively Coupled Plasma Mass Spectrometry (ICP-MS).
2. Evaluation of X-ray Fluorescence (XRF) Spectroscopy as a Screening Tool for Nanoscale Silver in FDA Regulated Food Products.
3. Nanosilver Migration from Food Contact Materials.

Analysis of Antibiotics and Excipients on Environmental Swab Materials Using High Resolution Mass Spectrometry.

Markham C. Luke, M.D., Ph.D.

Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH)
Silver Spring, MD

Background
M.D. and Ph.D. (Pharmacology), Johns Hopkins University School of Medicine
Board-Certified – Dermatology
Prior work as Attending Physician, Bethesda National Naval Medical Center
FDA Experience – 13 years

Research Interests
The Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH) conducts premarket review of cutting edge therapeutic and diagnostic device technologies. This component of the FDA evaluates the safety and effectiveness of new medical devices prior to their introduction into the marketplace.

Dr. Luke has research interests in clinical study design, clinical endpoints assessment, and scale development (including patient-reported outcomes) for both efficacy and safety determination of medical products. Specific attributes of medical devices and their impact on blinding and variability when used in the hands of clinicians and impact on clinical trial validity and outcome are currently being assessed. Dr. Luke has over 11 years of regulatory experience in clinical evaluation of device, drug, and biological products at the Food and Drug Administration.

Beverly Lyn-Cook, Ph.D.

Coordinator, NCTR Women's Health Research Program, Office of the Associate Director of Regulatory Activities
National Center for Toxicological Research

Background
Cell and Molecular Biology - Ph.D.
FDA Experience - 22 years

Research Interests

- Pharmacogenomics and Personalized Medicine
- Sex Differences in Drug Toxicity and Adverse Drug Reactions
- Epigenetic and Genetic Regulation of Drug Transporters
- Mechanisms Involved in Lupus Etiology
- Mechanistic Action of Dietary Agents and Cancer Drugs in Pancreatic and Breast Cancer (nutrigenomics)

Marian E. Major, Ph.D.

Office of Vaccine Research and Review (OVRR)
Center for Biologics Research and Evaluation (CBER)
NIH Campus, Bethesda, MD

Background
B.Sc. Hons. – University of Warwick, UK
Ph.D. – University of Warwick, UK
FDA Experience – 10 years

Research Interests
Hepatitis C virus (HCV) is a serious public health concern, there is no vaccine and 85 percent of people that become infected with the virus develop persistent infections that can, in later life, lead to severe liver problems such as cirrhosis or hepatocellular carcinoma (HCC). HCC is one of the few cancers increasing in frequency and mortality in the U.S., studies show that ~50% of HCC cases occur as a result of chronic HCV infection. This research program focuses on understanding the immunobiology and pathogenesis of HCV through studies in the following areas:

The identification of immunological correlates of protection. This work involves the analysis of Tcell and antibody responses. We are analyzing the specificity and phenotypes of antibody and Tcells induced following vaccination and comparing these with the types of responses induced during natural HCV infections. These studies will provide important biomarkers to be used in predicting the effectiveness of vaccine-induced immune responses.

Development of neutralization tests for HCV and efficient induction of cross-neutralizing antibodies. An important goal of any antibody based vaccine is the induction of potent and effective antibodies that can neutralize all variants of the virus. Cross neutralizing antibodies have been isolated from infected patients but the challenge remains of how to induce these antibodies with a recombinant vaccine. We are focusing on systems that can induce potent neutralizing antibodies in vivo and tests in vitro to analyze the ability of antibodies to neutralize all genotypes of HCV. Thereby identifying the most cross reactive immune responses that will protect against the greatest number of HCV isolates.

Elizabeth Mansfield, Ph.D.

Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)
Center for Devices and Radiological Health (CDRH)
Silver Spring, MD

Background
Ph.D. – Johns Hopkins University

Katherine Serrano, B.S.

Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)
Center for Devices and Radiological Health (CDRH)
Silver Spring, MD

Background
B.S. – University of Minnesota, Twin Cities

Research Interests
Since the implementation of the Medical Device Amendments (MDA) of 1976 FDA has generally exercised enforcement discretion and not enforced applicable regulations with respect to Laboratory Developed Tests (LDTs), a class of *in vitro* diagnostics that are manufactured, including being developed and validated, and offered, within a single laboratory. Since 1976, the nature of laboratory developed testing has changed dramatically. Today, many LDTs are becoming more complex, and diagnostic tests are playing an increasingly important role in clinical decision making and disease management, particularly in the context of personalized medicine. However, LDTs that have not been properly validated for their intended use put patients at risk. Risks include missed diagnosis, wrong diagnosis, and failure to receive appropriate treatment. In response to these public health concerns, the Agency is in the process of reconsidering its policy of blanket enforcement discretion over most LDTs. At this time, FDA believes that a risk-based application of oversight to LDTs is the appropriate approach to achieve the desired public health goals, and to assure that tests used in the provision of health care, whether developed by a laboratory or other manufacturer, are safe and effective.

Scott McNamee, Ph.D.

Office of Compliance (OC)
Center for Devices and Radiological Health (CDRH)
Silver Spring, MD

Background
Ph.D. – Material Science Engineering, Cornell University
FDA Experience – 18 years

Research Interests
Dr. McNamee's primary training has been in the area of material science engineering, which seeks to understand the relationships between the structure of materials and their properties. He has also been working in the area of transmissible spongiform encephalopathy (TSE) as it relates to medical devices that utilize animal tissues (primarily bovine) and the risks to the public from human TSEs such as Creutzfeld-Jacob Disease. His current work for the Office of Compliance includes understanding the risks and benefits of nanotechnology in the manufacture of medical devices, keeping abreast of the advances in regenerative medicine (also known as tissue engineering), and being part of the review of medical device failures resulting in recalls. Failure analysis, or root cause analysis, is critically important to the Center's work in Compliance, and the role that climate change and natural disasters may have in such failures will be one focus of this proposed project.

Tahseen Mirza, Ph.D.

Office of Pharmaceutical Science (OPS)
Center for Drug Evaluation and Research (CDER)
Silver Spring, MD

Background
Ph.D. – Pharmaceutical Sciences
FDA Experience – 1 year

Research Interests
My current interest is to develop *in vitro* models by identifying proper dissolution equipment and media and then use the *in vitro* data to predict the *in vivo* pharmacokinetic profile of a drug. Model compounds ranging from biological safety cabinets (BSC II) (low solubility and high permeability) to extended release dosage forms will be utilized. This work will enable us to develop better *in vitro* models so that FDA can grant faster post approval changes and mandate fewer clinical studies.

Megan Moynahan, M.S.

Office of the Center Director (OCD)
Center for Devices and Radiological Health (CDRH)
Silver Spring, MD

As Associate Director for Technology and Innovation (Acting), Megan directs the Center's Entrepreneurs in Residence program, a White House sponsored program that brings thought leaders into agencies to solve challenging problems. Targeting the Innovation Pathway, the EIR team of medical device innovators, business process innovators, and visionaries launched the End Stage Renal Disease Innovation Challenge in January, 2012, to spur medical device innovation for patients with ESRD. The team launched Innovation Pathway 2.0 on April 9, 2012, a streamlined regulatory pathway for pioneering medical devices that was built using lean start-up techniques. In 2010, Megan led the CDRH External Defibrillator Improvement Initiative, an effort to use FDA's regulatory oversight and public health influence to improve the performance of external defibrillators. Megan brings insight into the unique culture and workings of FDA's Center for Devices and Radiological Health, having over 16 years experience at FDA including six years as the branch chief for the premarket branch responsible for new pacemakers and defibrillators. Her successful cross-functional working group became the model for a Center-wide reorganization in 2008. In 2009, she was the chief architect for the Center's Signal Escalation program, a Center-wide business process focused on product safety that was cultivated as an in-house "start-up". Megan has been a member of the Office of the Center Director since 2008. Her background is in biomedical engineering with emphasis on electrical engineering and control systems. Her current areas of focus on the innovation team include wireless telemetry, continuous physiological monitoring, biosensors, and robotics.

Anne Pariser, M.D.

Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
Silver Spring, MD

Background
M.D.
FDA Experience – 10 years

Research Interests
To develop and improve regulatory science for therapies intended for the treatment of rare diseases from early phase drug development through marketing approval. This research would include a detailed analysis of the level of evidence used to support prior drug approvals for Orphan drugs, identification of factors that impede the development of products intended to treat rare diseases, and investigation and innovation into how to further drug development for rare diseases.

Renate Reimschuessel, V.M.D., Ph.D.

Office of Research
Center for Veterinary Medicine (CVM)
Laurel, MD

Background
B.A. – University of Pennsylvania
V.M.D. – University of Pennsylvania College of Veterinary Medicine
Ph.D. – University of Maryland
FDA Experience – 12 Years

Research Interests
Dr. Reimschuessel started veterinary practice in 1981, specializing in exotic animal medicine. In 1989 she obtained a Ph.D. in pathology, with a focus on aquatic animal responses to toxicant induced injury. She directed the Aquatic Pathobiology Center at University of Maryland School of Medicine until 1999 when she joined FDA to head up CVM's Aquaculture Research Program. Her research interests include:

- Therapeutant Development for Aquaculture;
- Pharmacokinetics and Species Grouping for Drug Approvals, Antimicrobial susceptibility testing;
- Melamine related renal injury and Feed Contamination/Adulteration – Recently she has become the Program Director for CVM's Veterinary Laboratory Response Network (VEtlRN) which will work with veterinary diagnostic laboratories to investigate potential feed contamination/adulteration events.

Anita Richardson, M.A.S.

Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
Rockville, MD

Background
B.S. – Medical Technology
M.A.S. – Business Administration
FDA Experience – 20 years

Laura K. Schnackenberg, Ph.D.

Division of Systems Biology (DSB)
National Center for Toxicological Research (NCTR)
Jefferson, AR

Background
Ph.D. – Analytical Chemistry
FDA Experience – 7 Years

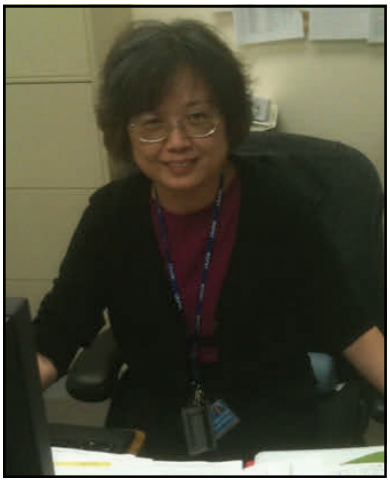
Research Interests
Metabolomics, biomarkers of toxicity and disease, nuclear magnetic resonance (NMR) spectroscopy, liquid chromatography (LC), solid phase extraction (SPE), magic angle spinning (MAS) NMR

Vicki Seyfert-Margolis, Ph.D.

Office of the Chief Scientist (OCS)
Office of Regulation Science and Critical Path (ORSCP)
Office of the Commissioner (OC)
Silver Spring, MD

Background
Ph.D. in Immunology – University of Pennsylvania, School of Medicine, Philadelphia, PA
B.S. in Biochemistry – University of the Sciences, Philadelphia, PA
FDA Experience – 1 year

Research Interests
Vicki Seyfert-Margolis, Ph.D., serves as the Senior Science Advisor to the FDA's Chief Scientist in the mission of upgrading science, with a focus on bioinformatics and advancing regulatory science. She has most recently been Chief Scientific Officer at Immune Tolerance Network, a non-profit consortium of researchers seeking new treatments for diseases of the immune system; and an Adjunct Associate Professor with the Department of Medicine at the University of California- San Francisco. Prior to that, Seyfert-Margolis was a program director in innovative scientific research at the National Institute of Allergy and Infectious Diseases, National Institutes of Health. Dr. Seyfert-Margolis research interests are: Immunology, biomarker development, advancing scientific computing environment/high density data, health information technology, validation and standards development.



Y. Carol Shieh, Ph.D.

Division of Food Processing Science and Technology (DFPST)
Center for Food Safety & Applied Nutrition (CFSAN)
Summit-Argo, IL

Background
M.S. – Food Microbiology, University of Georgia
Ph.D. – Food Microbiology, Cornell University
Research Faculty – University of North Carolina, Chapel Hill; and Tulane University School of Medicine
FDA Experience - 14 years

Research Interests Virus survival in foods during storage and processing conditions, norovirus cross-contamination/transfer rates, virus diversity in naturally contaminated foods, and virus replication in mammalian cells

Sithu D. Sudarsan, Ph.D.

Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)
Silver Spring, MD

Background
B.E. (Electronics and Communication Engineering), Madurai Kamaraj University, India
M.S. (Systems and Information), Birla Institute of Technology and Science, India
Ph.D. – Applied Science/Applied Computing, University of Arkansas at Little Rock, USA

Research and Development Experience – 20+ years
FDA – since 2008

Research Interests
The Division of Electrical and Software Engineering (DESE) under the Office of Science and Engineering Laboratories, conducts research, participates in device review activities, develops consensus standards both domestic and international, develops regulatory guidance, tests forensic and regulatory samples, and provides educational programs in the area of electrical engineering and software.

Specifically, the semantic mining research at DESE is geared to uncover hidden safety signals in real-time by analyzing unstructured natural language text in large regulatory document repositories. These document repositories continue to grow. We aim for very high recall and precision. We use Information Retrieval, Machine Learning, Topic Modeling, as well as Natural Language Processing techniques in our research. Dictionaries, ontologies, standards and guidance documents are some of the reference sources. We work in close collaboration with the High Performance Computing Center.

Raymond Philip Yeager, Ph.D.

Office of Science (OS)
Center for Tobacco Products (CTP)
Rockville, MD

Background
Ph.D. – Pharmacology and Toxicology, Virginia Commonwealth University
M.S. – Environmental Microbiology and Toxicology, University of Florida
Experience with patent application review of drugs and devices at the U.S. Patent & Trademark Office and risk assessment consulting
FDA Experience – 1 year

Research Interests
The Office of Science supports the Center for Tobacco Products by providing sound scientific evidence for implementation of the Family Smoking Prevention and Tobacco Control Act. The Office of Science reviews applications for substantial equivalent tobacco products, new tobacco products, and modified risk tobacco products. Evaluation of modified risk products requires the consideration of the risks of tobacco products to public health both at the individual and population level. In the framework of quantitative risk assessment research, concerns include:

- Methods of reporting and analyzing constituent concentrations in tobacco products;
- Analysis of exposure parameters in diverse tobacco-using populations;
- Toxicological basis of dose-response relationships between constituents and tobacco-related disease;
- Assessing the risks of tobacco products to users and non-users.

Jiyoung M. Dang, Ph.D.

Division of Surgical, Restorative, and Orthopedic Devices (DSROD)
Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH)
Silver Spring, MD

Background
Ph.D. – Biomedical Engineering, The Johns Hopkins University School of Medicine
B.S. – Biomedical Engineering, The Johns Hopkins University School of Engineering

Research and Regulatory Interests
Dr. Dang joined the FDA as a scientific reviewer in 2007 shortly after completing her Ph.D. thesis in the field of tissue engineering and regenerative medicine. In addition to premarket product review, she is involved in standards review and post-market issue management teams. She participates in various CDRH-CBER inter-Center activities related to regenerative medicine, including consultative review of cell-scaffold products, organization of workshops/seminars, and journal clubs. Dr. Dang has review expertise in surgical mesh devices and other polymer/biomaterials based products intended for tissue reconstruction or repair.

Mark H. Lee, Ph.D.

Division of Cellular and Gene Therapies (DCGT)
Office of Cellular, Tissue, and Gene Therapies (OCTGT)
Center for Biologic Evaluation and Research (CBER)
Rockville, MD

Background
Postdoctoral Fellowship Matrix/Integrin Biology – Institute of Medicine & Engineering/School of Medicine (PENN)
Ph.D. Bioengineering – University of Pennsylvania
M.S. Polymer Science – University of Connecticut Polymer Program
B.S.E. Bioengineering – University of Pennsylvania

Research and Regulatory Interests
Dr. Lee joined the FDA in 2008 after over 10 years of active interdisciplinary research in the fields of biomaterials and tissue engineering/regenerative medicine (TE/RM). In addition to his role as primary reviewer for biologics, devices and combination products submissions as a part of the Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER), Dr. Lee has spent time at the Center for Devices and Radiological Health (CDRH) as a visiting review scientist in 2010. He actively participates in and leads many Cross-Center efforts such as the Tissue Engineering & Regenerative Medicine Steering Committee and the Annual FDA Forum on Devices and Biologics Used in Regenerative Medicine which he co-chairs. Dr. Lee's regulatory interests include the harmonization of review practices and policies for biologics, medical devices and combination products used as regenerative therapies. He regularly engages in outreach efforts and has delivered numerous presentations and publications regarding FDA's regulation of Regenerative Medicine products.

Elias Mallis, B.S.

Division of Small Manufacturers, International, and
Consumer Assistance (DSMICA)
Office of Communication, Education, and
Radiation Programs (OCER)
Center for Devices and Radiological Health (CDRH)
Silver Spring, MD

Background
B.S. – Electrical Engineering, University of Maryland at College Park
FDA Experience – 18 years

Regulatory Interests
Over his career at CDRH, Mr. Mallis has served in a variety of regulatory roles. As a senior scientific reviewer, Mr. Mallis regulated products in the fields of gastroenterology, hemodialysis, extracorporeal therapeutics, obstetrics/gynecology, and combination products with a focus on tissue engineering. In subsequent leadership roles, Mr. Mallis oversaw the regulatory review scientific evaluation of cardiovascular medical devices, including combination device-biologic products. In his current role, Mr. Mallis leads an organization whose mission is to provide regulatory education to a vast range of external stakeholders of medical device and radiological health issues.

Steven S. Oh, Ph.D.

Division of Cellular and Gene Therapies (DCGT)
Office of Cellular, Tissue, and Gene Therapies (OCTGT)
Center for Biologic Evaluation and Research (CBER)
Rockville, MD

Background
Ph.D. – University of Michigan
Postdoctoral Fellowship – Johns Hopkins University School of Medicine and Massachusetts Institute of Technology
Faculty – Tufts University School of Medicine
FDA Experience – 3 years

Regulatory Interests
Dr. Oh's regulatory interests include device-biologic combination products, tissue engineered products, and devices with regenerative or therapeutic indications. He actively participates in scientific reviews of submissions, policy development, and staff training in these product areas in the Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER). Dr. Oh also spent time in Center for Devices and Radiological Health (CDRH) serving as a visiting review scientist from CBER. This unique experience has been crucial to Dr. Oh's understanding and appreciation of balanced approaches to biologic and device reviews and policy development. Upon returning to CBER from CDRH, Dr. Oh has founded Device Biologics Interest Group (DBIG) in 2008 providing a forum to regulatory staff in CBER and CDRH to learn and exchange ideas about regulations, standards, technologies, review practices, and policies applicable to devices and device-biologic combination products. He continues in the effort to harmonize review practices for combination products and devices regulated by CBER and CDRH.