

The Commissioner's Fellowship Program

Outcomes Evaluation Report

Initially released: April 10, 2014
Updated: December 6, 2017



Photo of Commissioner's Fellows

Introduction

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

Additionally, FDA is responsible for advancing the public health by helping to speed innovations that make medicines and foods more safe, effective and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.

FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Finally, FDA plays a significant role in the Nation's counterterrorism capability, by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats. Underpinning all of FDA's work is a well-trained scientific workforce.

Having a well-trained workforce has been a primary goal of the Federal government as evidenced in the establishment of the Human Capital Assessment and Accountability Framework (HCAAF) and the Chief Human Capital Officers Act, which carries out functions in 5 U.S.C. 1402. Within the HCAAF, succession planning, recruitment, and training are strategies identified to meet an organization's human capital needs. The Food and Drug Cosmetic Act, Section 742, also supports education through fellowships and scientific training.

In 2007, the Subcommittee on Science and Technology in its report to the Science Board noted that the "turnover rate in FDA science staff is twice that of other government agencies."¹ Although the report references a 2002 GAO report and FDA had hiring surges in FY 2008 and FY 2009, the Agency still faces workforce challenges. For example, the number of FDA staff eligible for retirement is expected to increase from 1,483 in FY 09 to 2,849 by the end of FY14—more than a quarter of FDA's workforce during this period.²

In 2007, the Science Board's Subcommittee on Science and Technology also reported that "the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities."³ The Subcommittee identified an "excellent staff with

¹ *FDA Science and Mission at Risk*, pg. 4, November 2007.

² *FDA 2010 Workforce Analysis, 2011-2012 Workforce Plan*.

³ *FDA Science and Mission at Risk*, pg. 2, November 2007.

cutting-edge scientific expertise appropriate to the mission”⁴ as crucial for a strong scientific foundation at FDA, yet found FDA's recruitment and retention, professional development, and external collaborations to be deficient.

Summary

To meet the scientific workforce challenges, in 2008, FDA launched the [Commissioner’s Fellowship Program](#) (CFP) to achieve three goals:

- 1) Attract top-tier scientists to FDA to address regulatory science issues through mentored projects of high priority to the Agency
- 2) Provide regulatory science training
- 3) Serve as a potential recruiting tool.

The first CFP Class of 2008 graduated in September 2010. To date, the CFP classes starting in 2008, 2009, 2010, 2011, 2012, 2013, 2014, and 2015 classes have graduated.

Attracting Scientists to FDA

Every year, hundreds of applicants have applied to FDA’s CFP, vastly in excess of available positions. There have been 973, 725, 642, 513, 294, 204, 222, and 136 applicants for the 2008, 2009, 2010, 2011, 2012, 2013, 2014, and 2015 classes, respectively.

Number of Applications and Fellows Selected

	2008	2009	2010	2011	2012	2013	2014	2015
Applications	973	725	642	513	294	204	222	136
Fellows Selected	50	50	45	32	22	13	16	18

Completing Regulatory Science Training

To graduate, Fellows must complete three requirements:

- 1) [5 required courses](#) that emphasize core disciplinary needs to provide a solid base for regulatory science.

⁴ FDA Science and Mission at Risk, pg. 2, November 2007.

- 2) A regulatory science project addressing a high-priority need under the mentorship of an established FDA scientist.
- 3) Substantive engagement in regulatory/review work.

Since 2008, **226 Fellows** have completed the required training and graduated from the program.

Contributing to FDA's Regulatory Science Activities

The [2008](#), [2009](#), [2010](#), [2011](#), [2012](#), [2013](#), [2014](#), and [2015](#) CFP graduates have addressed 48, 50, 36, 30, 18, 10, 16, and 18 regulatory science projects respectively.

Center Regulatory Science Projects

Center Projects	2008	2009	2010	2011	2012	2013	2014	2015	Total
Center for Biologics Evaluation and Research (CBER)	9	6	5	5	3	3	2	3	27
Center for Drug Evaluation and Research (CDER)	7	6	7	3	3	1	2	3	26
Center for Devices and Radiologic Health (CDRH)	6	11	4	8	2	2	1	2	31
Center for Tobacco Products (CTP)				1	1		1		2
Center for Food Safety and Applies Nutrition (CFSAN)	7	6	4	2	3	1	2	2	22
Center for Veterinary Medicine (CVM)	7	7	4	2					20
National Center for Toxicologic Research (NCTR)	7	7	7	3	4	3	3	4	28
Office of Regulatory Affairs		2	3	4	2	3	5	5	11
Office of the Commissioner	5	5	2	2					14
Total Regulatory Science Projects	48	50	36	30	18	10	16	18	226

Since the publication of the [FDA Regulatory Science Strategic Plan](#) in August 2011, there have been 30 Regulatory Science projects addressed by the 2011 CFP Graduates, 18 Regulatory Science projects addressed by the 2012 CFP Graduates, 10 Regulatory Science projects addressed by the 2013 CFP Graduates, 16 Regulatory Science projects addressed by the 2014 CFP Graduates, and 18 Regulatory Science projects addressed by the 2015 CFP Graduates.

CFP Fellows Regulatory Science Priority Area Projects

Regulatory Science Priority Areas	Number of CFP Class of 2011 Fellows Projects	Number of CFP Class of 2012 Fellows Projects	Number of CFP Class of 2013 Fellows Projects	Number of CFP Class of 2014 Fellows Projects	Number of CFP Class of 2015 Fellows Projects
Transform Toxicology to Enhance Product Safety	2	4	2	3	2
Stimulate Innovation in Clinical Trials and Personalized Medicine	3	2			2
Support New Ways to Improve Product Manufacturing and Quality	3	0	1		3
Ensure FDA Readiness to Evaluate Innovative Emerging Technologies	12	4	2	7	5
Harness Data through Information Sciences to Improve Health Outcomes	2	2	1	4	
Implement a New Prevention-Based Food Safety System	6	4	1	1	3
Support Medical Countermeasures Development to Protect National Health and Security	2	2	3	1	3
Total	30	18	10	16	18

The CFP Graduates have represented FDA with [262 regulatory science presentations and 196 publications](#). Their work earned 26 of them Center or FDA Honor Awards.

Public Health Impact of CFP Projects

The realized Agency and public health impacts of the Commissioner's Fellowship Program are summarized in the following section. The projects highlighted below have been selected by the CFP Advisory Board to be presented FDA-wide prior to graduation. See the public abstracts for these projects on the [CFP's public website](#). Appendix A lists the completed projects for Classes 2011-2015.

[Transform Toxicology to Enhance Product Safety](#)

Thirteen regulatory science projects have been completed by the Classes of 2011-15 that addressed modernizing toxicology to improve product safety. One project from the Class of 2011 (CTP), was *An Assessment of the Risks Associated with Childhood Exposure to Environmental Tobacco Smoke (ETS) Similarities*. After two years, "this project led to identification of a number of data gaps, development of a model to estimate exposure, and a preliminary quantification of the risks associated with a set of ETS harmful and potentially harmful constituents. This project lays the groundwork for what could potentially be an important factor in regulatory decisions at the Center for Tobacco Products." Another in this area, a project from the Class of 2014 (NCTR), was *The Development and Validation of EpiComet-Chip, a Modified High-Throughput Comet Assay for the Assessment of DNA Methylation Status*. "The successful application of this novel technology will aid hazard identification and risk characterization of FDA-regulated products, while providing utility for investigating epigenetic modes of action of agents in target organs, since the assay is amenable to cells in culture or nucleated cells from any tissue." The Classes of 2016 and 2017 have four projects in progress in this area.

[Stimulate Innovation in Clinical Evaluations and Personalized Medicine](#)

Seven regulatory science projects have been completed by the Classes of 2011-15 that addressed Stimulating Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes. A project from the Class of 2012 (CDER) under this area was *Construction of a Drug Transporter Database and Utilization of the Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulation to Predict and Analyze Transporter-mediated Drug-drug Interactions (DDIs)*, and the fellow and preceptor reported that, "The availability of both mechanistic static and dynamic PBPK models for statins will provide a powerful modeling tool to evaluate DDIs on statins, and contribute to the Agency's mission of ensuring safety of drug products and protecting the public health." The Classes of 2016 and 2017 have eight projects in progress in this area.

[Support New Approaches to Improve Product Manufacturing and Quality](#)

Seven regulatory science projects have been completed by the Classes of 2011-15 that addressed Supporting New Approaches to Improve Product Manufacturing and Quality. A project from the Class of 2013 (ORA) under this area was, *Development of a field capable device designed to reduce environmental sampling analysis times from 5 days to hours*, and the fellow and preceptor reported that, “A system as detailed in this report could be used as a platform for the detection of multiple analytes with a single matrix test. FDA should continue to develop such technologies and investigate the incorporation of such devices that are capable of data transmission into all points of the food chain for a fundamental change in how FDA does its work. With the successful adoption of such technologies by industry, each stage of the food chain: 1) production, 2) storage, 3) delivery, and 4) consumption, could be monitored in a proactive manner to identify and remove risks.” The Classes of 2016 and 2017 have six projects in progress in this area.

[Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

Thirty regulatory science projects have been completed by the Classes of 2011-15 that addressed Ensuring FDA Readiness to Evaluate Innovative Emerging Technologies. A project from the Class of 2014 (ORA) under this area was, *Application of Aptamer technology in the rapid detection, capture and concentration of foodborne pathogens from complex sample matrices*, and the fellow and preceptors final conclusions for the FDA were, “Rapid and timely detection of foodborne pathogens before public distribution of suspect food products is central to the FDA’s efforts to prevent foodborne disease outbreaks. This study successfully designed, selected, and characterized DNA aptamers specific to E. coli O157:H7, a common foodborne pathogen. Unlike antibodies, aptamers are highly stable molecular probes that are amenable to easy chemical modifications and customization for applications in a wide range of physiological and non-physiological conditions. Although the aptamers selected in this study still require additional validation studies, they remain promising candidates for application in E. coli O157:H7 rapid detection technologies, such as biosensors and in vitro biochemical assays. The selection of quality aptamers specific to whole cell targets is a challenging multistep process. The published aptamer selection method optimized in this study will help guide scientists in the selection of quality aptamers worldwide. Given the well-documented value of aptamers as molecular probes and potential applications in medicine and diagnostics, it is recommended that FDA commit more resources and scientists to the study and development of aptamer-based regulatory science technologies.” The Classes of 2016 and 2017 have five projects in progress in this area.

[Harness Diverse Data through Information Sciences to Improve Health Outcomes](#)

Nine regulatory science projects have been completed by the Classes of 2011-14 that addressed Harnessing Diverse Data through Information Sciences to Improve Health Outcomes. A project from the Class of 2013 (CBER) under this area was, *Analysis of safety profiles across licensed vaccines*. The fellow and preceptor reported that, “Our findings demonstrated that QIVs and TIVs have comparable safety profiles from a clinical perspective. This is consistent with the findings in multiple published studies in which pairs of QIVs and TIVs were compared. This meta-analysis provides more precise estimates of the safety of QIVs versus TIVs, and should provide reassurance regarding the safety of QIVs.” The Class of 2017 has two projects in progress in this area.

[Implement a New Prevention-Focused Food Safety System to Protect Public Health](#)

Fifteen regulatory science projects have been completed by the Classes of 2011-15 that addressed Implementing New Prevention-Focused Food Safety Systems to Protect Public Health. A project from the Class of 2014 (CFSAN) under this area was, *The role of Whole Genome Sequencing (WGS) in foodborne illness source attribution and its impact on regulatory science*. The fellow and preceptor concluded that, “WGS is a powerful tool that FDA and other federal agencies can use in protecting and promoting public health by not only decreasing the length and severity of an outbreak with its enhanced ability to link a clinical isolate to the source but also by its potential to be used to prevent an outbreak from ever occurring.” The Class of 2016 has four projects in progress in this area.

[Support Medical Countermeasures Development to Protect Against Threats to U.S. and Global Health and Security](#)

Eleven regulatory science projects have been completed by the Classes of 2011-15 that addressed Facilitating the Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security. A project from the Class of 2013 (CBER) under this area was, *Protecting Health Care Workers from Airborne Transmitted Disease via Use of Respiratory Protective Devices: A Gap Analysis of Regulatory Science in the Context of Current Practice and Regulatory Policy to Inform Medical Countermeasures for Pandemic Preparedness*. The fellow and preceptor summarized their project as follows, “Medical countermeasures (MCMs) are drugs, biologics, and devices that can be used to safeguard public health against naturally occurring and man made threats. Respiratory protective devices (RPDs) are an example of an MCM that play an important role in protecting health care workers (HCWs) employed in areas where patients may be infected with airborne transmitted diseases such as influenza and tuberculosis. In the event of an influenza pandemic (such as H1N1 in 2009), the need for RPDs may far

outpace the supply. This results in device shortages which poses a serious public health problem. In anticipation of device shortages in a pandemic, several preparedness strategies for increasing and extending the RPD supply have been proposed. However, these approaches lead to additional challenges in regulatory science, regulatory policy, and healthcare practice which must be comprehensively explored in order to bolster pandemic preparedness. The broad objective of this project is to enhance preparedness in the event of an airborne transmitted disease pandemic.” The Classes of 2016 and 2017 have zero projects in progress in this area.

[Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products](#)

The Class of 2016 has two projects in progress in this area.

Fellows Retained at FDA

Of the 226 CFP graduates to date, FDA has retained 77% (n=173). Academia and industry have also hired graduates.

CFP Fellows’ Employment at Graduation

	2008	2009	2010	2011	2012	2013	2014	2015	Total
Fellows	50	50	45	32	22	13	16	18	246
Hired									
Fellows	48	50	36	30	18	10	16	18	226
Graduated									
Retained	39	38	28	19	14	8	13	14	173
at FDA									
Academia	4	4	3	3	1				15
Industry	3	1	3	2			1		10
Other	2	7	2	6	3	2			22

FDA Product Centers Hiring Commissioner's Fellows at Graduation

Fellows FDA Retained	CBER	CDER	CDRH	CTP	CFSAN	CVM	ORA	NCTR	OC
2008 (39)	4	5	9	2	5	7	0	4	3
2009 (38)	2	4	14	1	4	5	1	4	3
2010 (28)	1	9	8	0	4	1	1	3	1
2011 (19)	0	5	8	2	0	1	0	2	1
2012 (14)	2	4	4	0	1	0	2	1	0
2013 (8)	2	1	4	1	0	0	0	0	0
2014 (13)	3	3	2	1	2	0	1	1	0
2015 (13)	2	5	3	0	0	1	1	1	0
Total	16	36	52	7	16	15	6	16	8

The 226 graduates of 100 men and 126 women represent different ethnic groups.

Ethnicity of Graduates

Ethnicity	2008	2009	2010	2011	2012	2013	2014	2015
White	19	23	16	12	7	6	6	8
Asian	22	19	13	16	10	2	9	7
Hispanic/ Latino	2	3	2	0	0	0	0	2
African American	5	5	5	2	1	2	1	1

Appendix A: FDA Scientific Priority and CFP Projects - Classes 2011- 2015

Transform Toxicology to Enhance Product Safety

1. *An Assessment of the Risks Associated with Childhood Exposure to Environmental Tobacco Smoke*, Fellow Brian E. Erkkila, Ph.D. and Preceptor Raymond Yeager, Ph.D. (CTP), 2011
2. *Assessment of mitochondrial ultrastructure and function after ketamine treatment in the developing rat brain*, Fellow Trisha Eustaquio, Ph.D. and Angel Paredes, Ph.D. (NCTR), 2012
3. *Characterization of the TK9 Exome by 454 Next Generation Sequencing*, Fellow Javier Revollo, Ph.D. and Vasily Dobrovolsky, Ph.D. (NCTR), 2012
4. *Confirmative Neuropathology studies with MRI Imaging and Informatics*, Fellow Srinivasulu Chigurupati, Ph.D. and Serguei Liachenko, M.D., Ph.D. (NCTR). 2012
5. *Chromatin structural state dynamics during NAFLD associated liver carcinogenesis*, Fellow Mekonnen Lemma Dechassa, D.V.M., Ph.D. and Preceptors Frederick A. Beland, Ph.D. and Igor P. Pogribny, Ph.D. (NCTR), 2015
6. *Development and evaluation of a novel in vitro microRNA screening model system for the hazard identification of FDA-regulated products*, Fellow April Marrone, Ph.D. and Preceptors Igor Pogribny, M.D., Ph.D. and Fredrick Beland, Ph.D. (NCTR), 2013
7. *Development and Validation of EpiComet-Chip, a Modified High-Throughput Comet Assay for the Assessment of DNA Methylation Status*, Fellow Todd Townsend, Ph.D. and Preceptor Mugimane Manjanatha, Ph.D. (NCTR), 2014
8. *Enhancing Regulatory Review of Computational and Mathematical Modeling for Regenerative Medicine Products*, Fellow Ryan Ortega Ph.D. and Preceptors Alex M. Bailey, Ph.D., Tina Morrison, Ph.D., and Brian Pullin, Ph.D., (CBER/CDRH), 2015
9. *Evaluation of effects of nanoparticles on enteric microbiota and virobiota*, Fellow Aschalew Bekele, Ph.D. and Preceptor Sangeeta Khare (NCTR), 2013
10. *Investigation of Hemoglobin-induced pulmonary toxicity*, Fellow Narendranath Chintagari, Ph.D. and Abdu Alayash, Ph.D. (CBER), 2012
11. *Mechanistic Toxicological Evaluation of Engineered Nanomaterial Using a Human Stem Cell Model*, Fellow Jia Yao, Ph.D. and Preceptor Yongbin Zhang, Ph.D. (NCTR), 2014

12. *Pharmacokinetic Modeling: Prediction and Evaluation of Route Dependent Dosimetry of Bisphenol A in Rats at Different Development Stages*, Fellow Xiaoxia Yang, Ph.D. and Preceptor Jeffrey Fisher, Ph.D. (NCTR), 2011
13. *Predicting cardiac adverse events associated with tyrosine kinase inhibitors*, Fellow Shadia Zaman, Ph.D. and Darrel R. Abernethy (CDER), 2014

Stimulate Innovation in Clinical Trials and Personalized Medicine

1. *Clinical Trial Simulation as a Means to Improve Pediatric and Neonatal Drug Development Trials*, Fellow, Janelle Burnham, M.D. and Preceptor Dionna Green, M.D., (CDER), 2015
2. *Construction of a Drug Transporter Database and Utilization of the Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulation to Predict and Analyze Transporter-mediated Drug-drug Interactions (DDIs)*, Fellow Peng Duan, Ph.D. and Preceptor Lei Zhang, Ph.D. (CDER), 2012
3. *Developmental Effects on Warfarin Pharmacogenomics in Young Pediatric Patients*, by Fellow Jeremiah Momper, Pharm.D., Ph.D. and Preceptor Gilbert Burckart, Pharm.D. (CDER), 2011
4. *Establishing A Knowledge-base of Physiologically-based Pharmacokinetic (PBPK) Models to Support Regulatory Review*, Fellow Yuzhuo Pan, Ph.D. and Preceptor Ping Zhao, Ph.D. (CDER), 2012
5. *Identifying opportunities for personalization in the drug development pipeline*, Fellow: Oluseyi Adeniyi, Ph.D. and Preceptor Michael Pacanowski (CDER), 2015
6. *Improvement of Hepatitis C Virus (HCV) Vaccines through Phenotypic T-cell Analysis and Potency Assay Development*, Fellow Wendy Tan, Ph.D. and Preceptor Marian Major, Ph.D. (CBER), 2011
7. *The Role of ABC-Drug Transporters in Chemoresistance in Pancreatic Cancer: Assessing Drug Safety and Efficacy*, Fellow Li Pang, M.D. and Preceptor Beverly Lyn-Cook, Ph.D. (NCTR), 2011

Support New Ways to Improve Product Manufacturing and Quality

1. *Development of a field capable device designed to reduce environmental sampling analysis times from 5 days to hours*, Fellow Aaron Bandremer and Preceptor Stephen Torosian, Ph.D. (ORA), 2013
2. *Development of in vitro Models for the Prediction of in vivo Food Effect on Drugs*,

Fellow Ahsanul Haque, RPh, Ph.D., RAC and Preceptors Tahseen Mirza, Ph.D. and Mansoor Khan, Ph.D. (CDER), 2011

3. *Establishment of a database and meta-analysis of Chimeric Antigen Receptor T-cells targeting CD19 (CART19): Analysis of product characteristics and critical product attributes to guide chemistry, manufacturing, and control (CMC)*, Fellow Kimberly Shultz, Ph.D. and Preceptor Denise Gavin, Ph.D., (CBER), 2015
4. *Performance Evaluation of a Multiallergen Immuno Assay in Botanical Dietary Supplements and Spices*, Fellow Ronnie Pederson, Ph.D. and Preceptor Eric A.E. Garber, Ph.D., (CFSAN), 2015
5. *Proteomic Characterization of Multipotent Stromal Cells Seeded on Different Scaffolds to Uncover Osteogenic Differentiation Biomarkers*, Fellow Kristin Schultz-Kuszek, Ph.D. and Preceptor Michail Alterman, Ph.D. (CBER), 2011
6. *Science Policy and Compliance Program Risk-Modeling Related to the Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*, Fellow Prakash Rath, Ph.D. and Preceptor Anita Richardson, M.A.S., B.S., M.T. (ASCP) (CBER), 2011
7. *Synthesis, Surface functionalization, Quantification of coatings and their influence on Biological properties of Nanomaterials*, Fellow Sureshbabu Dadiboyena, Ph.D. and Preceptor Anil K. Patri, Ph.D., (NCTR), 2015

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

1. *Advancing Regulatory Science and Innovation in Stem Cells and Regenerative Medicine*, Fellow Michael Mendicino, Ph.D. and Preceptors Frank Weichold, M.D. and Vicki Seyfert-Margolis, Ph.D. (OC) (CBER Mentors: Steve Bauer, Ph.D. and Keith Wonnacott, Ph.D.), 2011
2. *Application of Aptamer technology in the rapid detection, capture and concentration of foodborne pathogens from complex sample matrices*, Fellow Geoffrey Kilibi, Ph.D. and Preceptor Christine Karbiwnyk, Ph.D. (ORA), 2014
3. *Application of next generation sequencing in subtyping *Listeria monocytogenes* and comparison with pulsed-field gel electrophoresis*, Fellow Xia Xu, Ph.D. and Preceptor Paul M. Morin, Sc.D. (ORA), 2014
4. *Computational Modeling of Device, Tissue, and Device-Tissue Interaction for Device Evaluation*, Fellow Clark Meyer, Ph.D. and Preceptor Nandini Duraiswamy, Ph.D. (CDRH), 2011
5. *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*, Fellow Cynthia J. Chang, D.Phil. and Preceptors Steven Oh, Ph.D., Mark H. Lee, Ph.D., Jiyoung Dang, Ph.D., and Elias Mallis, B.S. (CDRH), 2011
6. *Designing HIV-1 Vaccine Immunogens by Stabilizing gp120 with an Exposed CD4 Receptor Binding Site*, Paul Keller, Ph.D. and Ira Berkower, M.D., Ph.D. (CBER), 2012
 7. *Detection of Shiga Toxin-Producing Escherichia coli*, Fellow Laurie M. Clotilde, Ph.D. and Preceptor Andrew Lin, Ph.D. (ORA), 2011
 8. *Developing Guidance Documents for Research Use Only/Investigational Use Only Components in in-vitro Devices and Risk-based Classification of Novel in-vitro Devices*, Fellow Barbara Demby Abrams, M.D., J.D. and Preceptors Elizabeth Mansfield, Ph.D. and Katherine Serrano, B.S. (CDRH), 2011
 9. *Development and Application of LC-SPE-NMR Methods to Evaluate Biomarkers of Hepatotoxicity*, Fellow Katya Petrova, Ph.D. and Preceptor Laura Schnackenberg, Ph.D. (NCTR), 2011
 10. *Development and evaluation of novel strategies for characterizing high-order therapeutic protein structure during drug development and manufacture*, Fellow Wojciech Jankowski, Ph.D. and Preceptor Zuben Sauna, Ph.D. (CBER), 2014
 11. *Development of foodborne virus concentration method and its application in viral pathogen detection from food matrix*, Fellow Yan Zheng, Ph.D. and Preceptor Yuan Hu, Ph.D., (ORA), 2015
 12. *Development Methodologies for the Characterization of FDA Regulated Liposomal Products*, Fellow Ji-Young Park, Ph.D. and Preceptor Sean W. Linder, Ph.D. (ORA), 2011
 13. *Development of a Guidance Document for Ophthalmic Optical Coherence Tomography Imaging Devices*, Fellow Carol Lin, M.D. and Preceptor Eva Rorer, M.D. (CDRH), 2012
 14. *Development of a Quality Management System for the Office of In Vitro Diagnostics and Radiological Health*, Fellow Peter Tobin, Ph.D. and Preceptor Brendan O'Leary, (CDRH), 2014
 15. *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*, Fellow Jacqueline AM Yancy, Ph.D. and Preceptors Elizabeth Mansfield, Ph.D. and Katherine M. Serrano, B.S. (CDRH), 2011
 16. *Development of molecular diagnostic method that can rapidly identify Bacillus*

cereus and related species from food and environmental samples, Fellow Mohd Kabir Ph.D. and Preceptor Irshad Sulaiman, Ph.D (ORA), 2014

17. *Ensuring FDA readiness to regulate modern bone void filler devices: an investigation of regenerative terms used in premarket notifications and scientific literature*, Fellow: John Jameson, Ph.D. and Preceptor Aric D. Kaiser, Ph.D., (CBER/CDRH), 2015
18. *Evaluation and assessment of FDA review of bone void filler devices with increased regenerative properties without the use of biological factors*, Fellows Sarah Brittain, M.S. and Preceptors Mercedes Serabian, M.S. Elias Mallis, Ph.D. and Aric Kaiser, Ph.D. (Multi-Center Fellowship in Regenerative Medicine (CBER and CDRH)), 2013
19. *Evaluation of Additive Manufactured Products: Current scientific trends, regulatory challenges, and enhancement of FDA review*, Fellow Laura Ricles, Ph.D. and Preceptor Steven Oh, Ph.D.(CBER), 2014
20. *Evaluation of the Immunogenic Potential of Cell-based Regenerative Medicine Products*, Iwen Wu, Ph.D. and Preceptors Mercedes Serabian, M.S. Elias Mallis, Ph.D. and Aric Kaiser, Ph.D. (Multi-Center Fellowship in Regenerative Medicine (CBER and CDRH)), 2013
21. *Evaluation of regenerative medicine devices that produce a biological product at the patient point-of-care: Assessment of device and output controls and enhancement of FDA review*, Fellow Carolyn Yong, Ph.D. and Preceptors Kenneth Cavanaugh, Ph.D., Charles Durfor, Ph.D., and Steven Oh, Ph.D. (CDRH and CBER), 2012
22. *FDA Patient-Centered Outcomes Research (PCOR) Promoting Personalized Medicine*, Fellow Shifu Zhao, Ph.D. and Preceptors Frank Weichold, M.D. and Vicki Seyfert-Margolis. Ph.D. (OC), 2011
23. *Guidance Development for Future Medical Devices*, Fellow Anh Nguyen, M.D., MBA and Preceptor Markham Luke, M.D., Ph.D. (CDRH), 2011
24. *Method development in the detection of radioactive contamination of food products*, Fellow Clarence Rolle Ph.D. and Preceptor Stephanie L. Healey, Ph.D., (ORA), 2015
25. *Opportunities and challenges in applying existing biocompatibility standards for the safety evaluation of cardiovascular device-biologic combination products*, Fellow Carmen Gacchina Johnson, Ph.D. and Kenneth Cavanaugh, Ph.D., Charles Durfor, Ph.D. and Steven Oh, Ph.D. (CDRH and CBER), 2012
26. *Opportunities and Challenges of Using Standards for Premarket Review of Bone Regenerative Medicine Products at CBER and CDRH*, Fellow Diana M. Yoon and

- Preceptors Jiyoung M. Dang, Ph.D., Mark H. Lee, Ph.D., and Elias Mallis, B.S., (CBER and CDRH), 2011
27. *Rapid Diagnostic Method Development for the Detection and Differentiation of Campylobacter*, Fellow Ying-Hsin Hsieh, Ph.D. and Preceptor Irshad M. Sulaiman, Ph.D., (ORA), 2015
 28. *Resolving Priority Taxonomic Issues in Commercial Swimming Crabs that Impact Seafood Labeling in the United States*, Fellow Amanda Windsor, Ph.D. and Preceptor Jonathan R. Deeds, Ph.D., (CFSAN), 2015
 29. *Use of metal nanoparticles with Surface Enhanced Raman Spectroscopy (SERS) for qualitative and quantitative analysis of contaminants within FDA regulated products*, Fellow Yasith Nanaykkara, Ph.D. and Preceptor Sean Linder, Ph.D. (ORA), 2014
 30. *U.S. Medical Device Innovation (2000-2011): An Analysis of Regulatory Decision Points and Total Time-to-Market for PMA and De Novo Devices*, Fellow Charles Haggart, Ph.D. and Preceptors Megan Moynahan, Ph.D., Murray Sheldon, M.D. and Daya Ranamukhaarachchi, Ph.D. (CDRH), 2011

Harness Data through Information Sciences to Improve Health Outcomes

1. *Analysis of safety profiles across licensed vaccines*, Fellow Pin Zhang, M.D., Ph.D. and Preceptor Elizabeth Sutkowski, Ph.D. (CBER), 2013
2. *Assessing patterns of tobacco product use among US adults: descriptive findings from the Population Assessment of Tobacco and Health (PATH) study*, Fellow Yu-Ching Cheng, Ph.D. and Preceptor Nicolette Borek, Ph.D. (CTP), 2014
3. *A Scientifically Based Guidance to Facilitate Efficiency of Environmental Reviews of Food Contact Notifications involving Antimicrobial Compounds*, Fellow Catherine McCollum, Ph.D. and Preceptor Suzanne Hill (CFSAN), 2014
4. *Bayesian approaches to subgroup analysis*, Fellow Yu-Yi Hsu, Ph.D. and Preceptor Ram Tiwari, Ph.D. (CDER), 2014
5. *Likelihood Ratio Test (LRT) for Safety Signal Detections in Clinical Trials*, Fellow Yueqin Zhao, Ph.D. and Preceptor Ram Tiwari, Ph.D. (CDER), 2012
6. *Medical Device Adverse Event Labeling (MEDAL) – An Automated Text Mining Approach*, Fellow Yanna S. Kang, Ph.D. and Preceptors Sithu Sudarsan, Ph.D. and Brian Fitzgerald, B.Sc. (CDRH), 2011
7. *The Role of Natural History Studies in Drug Development for Rare Diseases*, Fellow Gumei Liu, Ph.D and Preceptor Anne Pariser, M.D. (CDER), 2011

8. *Sequencing Mycobacterial Strains Isolated from Tattoo Inks*, Fellow Silvia Secelean, Ph.D. and Preceptor Donna Williams-Hill, Ph.D. (ORA), 2014
9. *Streamlining Tobacco Industry Submissions to the FDA Center for Tobacco Products*, Fellow Krystl Haerian, M.D. and Li-Lun Chen, M.D. and Wendy Aaronson, M.S. (CTP), 2012

Implement a New Prevention-Based Food Safety System

1. *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*, Fellow Gajendiran Mahadevan, Ph.D. and Preceptor Oscar (Alberto) Chiesa, D.V.M., M.S., Ph.D. (CVM), 2011
2. *Developing a Universal Enrichment Broth for Foodborne Bacterial Pathogens*, Fellow Kirsten Hirneisen, Ph.D. and Donna Williams-Hill, Ph.D. (ORA), 2012
3. *Development and validation of an environmental testing method for the detection of *L. monocytogenes* in food processing environment*, Fellow Anita Khatiwara, Ph.D. and Preceptor Thomas Hammack, M.S. (CFSAN), 2012
4. *Development of a Liquid Mid-Density Micro Array Assay for the Detection of Food-Borne Enteric Viruses using Luminex® xMAP™ Technology*, Fellow Subrat Rout, Ph.D. and Preceptor Gary Hartman, M.A. (ORA), 2011
5. *Development of a Method to Concentrate Norovirus in Foods and Evaluation of Cell Culture System for Virus Propagation*, Fellow Absar Alum, Ph.D. and Preceptor Y. Carol Shieh, Ph.D. (CFSAN), 2011
6. *Development of screening methods for diarrhetic shellfish toxins and azaspiracid shellfish toxins using surface plasmon resonance and confirmation by LC-MS/MS for regulatory application in seafood*, Fellow Li Yang, Ph.D. and James M. Hungerford, Ph.D., (NCTR), 2015
7. *Evaluation of incompatibility group IncFIB plasmid-mediated virulence in *Salmonella enterica**, Fellow: Bijay Khajanchi, Ph.D. and Preceptor Steven Foley, Ph.D., (NCTR), 2015
8. *Investigation of Etiology of Chicken Jerky Treat Related Renal Failure and Fanconi Syndrome in Dogs*, Fellow Olgica Ceric, Ph.D. and Preceptor Renate Reimschuessel, Ph.D. (CVM), 2011
9. *Method development for rapid detection of *Cronobacter sakazakii**, Fellow Katie Swensen-Segars, Ph.D. and Preceptor Irshad Sulaiman, Ph.D. (ORA), 2013
10. *Method development for the screening and quantification of undeclared drugs in*

dietary supplements using ultra-high performance liquid chromatography-quadrupole-orbitrap mass spectrometry, Fellow Flavia Morales-Garcia, Ph.D. and Preceptors Aref El-Demerdash, Ph.D. and Fenhong Song, Ph.D., (ORA), 2015

11. *Rapid Molecular Typing of Shiga Toxin-Producing Escherichia coli Using the Automated DiversiLab® Repetitive-Sequence-Based PCR System*, Fellow Kimberly Anderson, Ph.D. and Preceptor Sunee Himathongkham, Ph.D., D.V.M., M.P.V.M. (ORA), 2011
12. *Recommendations for Laboratory Surveillance and Screening of Pathogenic Escherichia coli in Food Products Using Molecular Methods*, Fellow Alifiya H. Ghadiali, Ph.D. and Preceptor Julia A. Kase, Ph.D. (CFSAN), 2011
13. *Role of Whole Genome Sequencing (WGS) in foodborne illness source attribution and its impact on regulatory science*, Fellow Eric Stevens, Ph.D. and Preceptor Peter Evans, Ph.D. (CFSAN), 2014
14. *Temporal Trends in Outbreak Attribution of Produce and Juices Compared to Other Food Groups*, Fellow Michael Bazaco, Ph.D. and Preceptor Debra Street, Ph.D. (CFSAN), 2012
15. *Validation of Extrusion Processing for Inactivation of Salmonella in Low Moisture Model Foods*, Fellow Niharika Mishra, Ph.D. and Preceptor John Larkin, Ph.D. (CFSAN), 2012

Support Medical Countermeasures Development to Protect National Health and Security

1. *Advancing the development of endpoints in TBI: Scientific, Clinical, Patient and Regulatory Considerations*, Fellow Lakshmi Kannan Ph.D. and Preceptor Allison Kumar, Ph.D., (CDRH), 2015
2. *Application of quantitative tools in deriving pediatric dosing for medical countermeasure products*, Fellow Rita Humeniuk, Ph.D. and Preceptor Dionna Green, M.D. (CDER), 2013
3. *Biological Role of the Cytokine p40 in Clearing Chronic Infections Caused by Vaccination with Francisella Tularensis Live Vaccine Strain (LVS)*, Fellow Jonathan Swoboda and Preceptor Karen Elkins, Ph.D. (CBER), 2011
4. *Design of a Sensitive & Specific Multiplex Platform for Pathogen Detection*, Fellow Bryan Grabias, Ph.D. and Preceptor Sanjai Kumar, Ph.D. (CBER), 2013
5. *Development of a common platform to assess neutralizing antibodies for pathogenic human viruses*, Fellow Stella Lee, Ph.D., and Preceptor Keith Peden, Ph.D., (CBER), 2015

6. *Development of medical countermeasures for treating Ebola virus disease*, Fellow Chia –Wen (Amy) Hsu, Ph.D. and Preceptor Jane Bai, Ph.D., (CDER), 2015
7. *Evaluating Changes in Host Transcriptome and Cellular Metabolism caused by exposure to Nanoparticles during Coronavirus and Norovirus infection as models of Enteric and Respiratory exposure*, Fellow Sudhakar Agnihothram, Ph.D. and Preceptor Marli Azevedo, Ph.D. (NCTR), 2014
8. *Effect of Extreme Weather Events on the Integrity and Safety of Medical Devices and Guidance toward Mitigating Future Challenges*, Fellow Jennifer Kelly, Ph.D. and Preceptor Scott McNamee. Ph.D. (CDRH), 2011
9. *Gene expression profiling in pulmonary, gastrointestinal and cutaneous epithelial cell lines after infection with Bacillus anthracis Sterne*, Fellow Bernard Marasa, Ph.D. and Preceptor Saeed Khan, Ph.D., (NCTR), 2012
10. *Protecting Health Care Workers from Airborne Transmitted Disease via Use of Respiratory Protective Devices: A Gap Analysis of Regulatory Science in the Context of Current Practice and Regulatory Policy to Inform Medical Countermeasures for Pandemic Preparedness*, Fellow Aftin Ross, Ph.D. and Preceptor Suzanne Schwartz, M.D. (CDRH), 2013
11. *Rapid Detection of Pathogens using Nanoparticles functionalized with Aptamers, with Realtime Analysis*, Fellow Justina Tam, Ph.D. and Preceptor Charles Clavet, Ph.D., (ORA), 2012