U.S. FOOD & DRUG ADMINISTRATION

The Commissioner's Fellowship Program

Summary Evaluation Report 2010-2020

Updated: November 30, 2020

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 746, also supports training. .

The CFP has been established to address the 2007 Subcommittee on Science and Technology report to the Science Board. This report 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] 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 cutting-edge scientific

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

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.

Outcomes

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, ten CFP classes have graduated.

Attracting Scientists to FDA

Every year, hundreds of applicants have applied to FDA's CFP, vastly in excess of available positions. Over the last 10 years, the CFP has attracted a total of 4113 applicants with an average of 14 applicants for every Fellow position (see Table 1).

Table 1. Number of Applications and Fellows Selected

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Applications	**973**	**725**	**642**	**513**	**294**	**204**	**222**	**136**	**222**	**182**
Fellows Selected	50	50	45	32	22	13	16	18	17	15

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, 256 Fellows have completed the required training and graduated from the program. See Table 2 for the number of completed regulatory science projects by Center.

Table 2. Center Regulatory Science Projects

Center Projects	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Center for Biologics Evaluation and Research (CBER)	9	6	5	5	3	3	2	3	4	1	**41**
Center for Drug Evaluation and Research (CDER)	7	6	7	3	3	1	2	3	2	4	**38**
Center for Devices and Radiologic Health (CDRH)	6	11	4	8	2	2	1	1		5	**40**
Center for Tobacco Products (CTP)				1	1		1		1	1	**5**
Center for Food Safety and Applies Nutrition (CFSAN)	7	6	4	2	3		2	2	2	1	**29**
Center for Veterinary Medicine (CVM)	7	7	4	2							**20**
National Center for Toxicologic Research (NCTR)	7	7	7	3	4	2	3	3	2		**38**
Office of Regulatory Affairs		2	3	4	2	2	5	5	5	3	**31**
Office of the Commissioner	5	5	2	2							**14**
Total Regulatory Science Projects	**48**	**50**	**36**	**30**	**18**	**10**	**16**	**17**	**16**	**15**	**256**

The CFP Graduates have represented FDA with 277 regulatory science presentations and 204 publications. Twenty-six CFP Graduates have earned 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 presented in Table 3 that lists the number of completed regulatory science projects for each FDA public health priority. Appendix A lists the completed projects for Classes 2011-2017 that align with the FDA's 2011 Regulatory Science priorities.

Table 3. Number of Regulatory Science Projects that Address FDA Public Health Priorities

FDA Public Health Priority	Number of Completed Regulatory Science Projects
Transform Toxicology to Enhance Product Safety	16
Stimulate Innovation in Clinical Trials and Personalized Medicine	15
Support New Ways to Improve Product Manufacturing and Quality	13
Harness Data through Information Sciences to Improve Health Outcomes	12
Implement a New Prevention-Based Food Safety System	19
Support Medical Countermeasures Development to Protect National Health and Security	11
Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products	2
Ensure FDA Readiness to Evaluate Innovative Emerging Technologies	36

Fellows Retained at FDA

Of the 256 CFP graduates to date, FDA has retained 76% (n=196). Academia and industry have also hired graduates. Table 4 presents the CFP Fellows' employment status at the time of graduation.

Table 4. CFP Fellows' Employment at Graduation

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Fellows Hired	50	50	45	32	22	13	16	18	17	15	**278**
Fellows Graduated	48	50	36	30	18	10	16	17	16	15	**256**
Retained at FDA	39	38	28	19	14	8	14	14	9	13	**196**
Academia	4	4	3	3	1						**15**
Industry	3	1	3	2			1		1		**11**
Other	2	7	2	6	3	2					**22**

FDA Product Centers Hiring Commissioner's Fellows at Graduation

Overall, the three medical product Centers (CBER, CDER, and CDRH) have hired the most CFP Fellows. Table 5 presents the Centers hiring of CFP Fellows.

Table 5. Center and Office Hiring of CFP Fellows

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 (14)	3	3	2	2	2	0	1	1	0
2015 (14)	2	5	3	0	0	1	2	1	0
2016 (9)	4	1	3		1				
2017 (13)	3	2	5	2	1				
Total	**23**	**39**	**60**	**9**	**18**	**15**	**6**	**16**	**8**

Demographics of CFP Graduates

The 256 graduates of 111 men and 145 women represent different ethnic groups with Whites (42%), Asians (44%), Hispanic/Latinos (3%) and African American (11%). Table 6 presents the ethnicity of CFP Fellows for each class.

Table 6. Ethnicity of CFP Graduates.

Ethnicity	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
White	19	23	16	12	7	6	6	7	8	3
Asian	22	19	13	16	10	2	9	7	4	11
Hispanic/Latino	2	3	2	0	0	0	0	2		
African American	5	5	5	2	1	2	1	1	4	1

Summary

The CFP has been successful accomplishing the three goals of a) attracting scientists, b) providing regulatory science training and c) retraining graduates. For 10 years, the CFP has attracted scientists from all over the world with applicants interested in regulatory science training. The program has been successful with its graduates who have been retained by FDA as well as hired by academia and industry.

The program has also demonstrated success by contributing to the public priorities of the Agency with data to inform regulatory decisions. Additionally, several of the regulatory science projects have been recognized with acceptance as presentations and publications at national and international conferences. As a result of their outstanding contributions, CFP graduates have received FDA or Center Honor Awards.

Appendix A: FDA Scientific Priority and CFP Regulatory Science Projects - Classes 2011-2017

Transform Toxicology to Enhance Product Safety

1. Assessment of Commonly Used Botanical Extracts in Cosmetic Skin Care Products, Fellow Zemin Wang, Ph.D. and Preceptor Nakissa Sadrieh, Ph.D., (CFSAN), 2017
2. *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
3. *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
4. *Characterization of the TK9 Exome by 454 Next Generation Sequencing*, Fellow Javier Revollo, Ph.D. and Vasily Dobrovolsky, Ph.D. (NCTR), 2012
5. *Confirmative Neuropathology studies with MRI Imaging and Informatics*, Fellow Srinivasulu Chigurupati, Ph.D. and Serguei Liachenko, M.D., Ph.D. (NCTR). 2012
6. *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
7. *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
8. *Developmental neurotoxicity evaluation of inorganic arsenic exposure*, Fellow Christopher L. Moore, Ph.D. and Preceptor Sherry A. Ferguson, Ph.D. (NCTR), 2016
9. *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
10. *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

11. *Evaluation of effects of nanoparticles on enteric microbiota and virobiota*, Fellow Aschalew Bekele, Ph.D. and Preceptor Sangeeta Khare (NCTR), 2013
12. *Investigation of Hemoglobin-induced pulmonary toxicity*, Fellow Narendranath Chintagari, Ph.D. and Abdu Alayash, Ph.D. (CBER), 2012
13. *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
14. *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
15. *Predicting cardiac adverse events associated with tyrosine kinase inhibitors*, Fellow Shadia Zaman, Ph.D. and Darrel R. Abernethy (CDER), 2014
16. Toxicological Evaluation of Flavorings Ingredients in Electronic Nicotine Delivery Systems (ENDS), Fellow Kamau Peters, Ph.D. and Preceptors Gladys Erives, Ph.D. and Luis Valerio Jr. Ph.D. (CTP), 2017

Stimulate Innovation in Clinical Trials and Personalized Medicine

1. *Advancing the development of biomarkers to detect and monitor drug-induced kidney injury*, Fellow Carolina Pacino Ph.D. and Preceptor Christopher Leptak, Ph.D. (CDER), 2016
2. *Advancing the Use of Electronic Health Records in Monitoring the Safety of Blood and Blood Products*, Fellow Joyce Obidi, Ph.D. and Preceptor Azadeh Shoaibi, Ph.D. (CBER), 2016
3. *Automated Data Visualization Tool to Map FDA-CDER's Public-Private-Partnership Deliverables*, Fellow Rama (Raju) Rayavarapu, Ph.D. and Preceptor Ameeta Parekh, Ph.D. (CDER), 2017
4. *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

5. *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

6. *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

7. *Development of structured submission tools for CLIA Waiver submissions,* Fellow Chelsea Virgile, Ph.D. and Preceptor: Peter Tobin, Ph.D. (CDRH), 2017

8. *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

9. *Evaluating and developing application of single cell sequencing in tumor early detection and treatment*, Fellow Qianghua Xia, Ph.D. and Preceptor Wenming Xiao, Ph.D. (NCTR), 2016

10. *Extrapolation of Adult Rheumatoid Arthritis Efficacy Data to Polyarticular Juvenile Idiopathic Arthritis,* Fellow Ramy Abdelrahman, M.D. and Preceptors Lynne Yao, MD; and Lily (Yeruk) Mulugeta, PharmD. (CDER), 2017

11. *Guidance for Multi-Reader Multi-Case (MRMC) Study Design and Results Analysis: A Hitchhikers Guide to MRMC Study Optimization,* Fellow Farzana Sharmin, Ph.D. and Preceptor Jeffrey Ballyns, Ph.D. (CDRH), 2017

12. *Identifying opportunities for personalization in the drug development pipeline,* Fellow: Oluseyi Adeniyi, Ph.D. and Preceptor Michael Pacanowski (CDER), 2015

13. *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

14. *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

15. *Surrogate Endpoints and Drug Approval*, Fellow Abena Agyeman, Ph.D. and Preceptor Christopher Leptak, Ph.D. (CDER), 2016

Support New Ways to Improve Product Manufacturing and Quality

1. *Development of FDA review tools to improve the quality of devices for weight reduction and metallic biliary stents,* Fellow Laura Gottschalk, Ph.D. and Preceptors Benjamin Fisher, Ph.D. and April Marrone, Ph.D., MBA (CDRH), 2017

2. *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

3. *Development of Lipids Profiling Method for Parenteral Lipid-Based Drug Delivery Systems,* Fellow Changguang Wang, Ph.D. and Preceptor Thilak Mudalige, Ph.D. (ORA), 2017

4. *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

5. *Enhancing Regulatory Science and Drug Development: Approaches To Advanced Manufacturing and Comparability of Cell-Based Therapeutics, Fellow Tal Hila Salz, Ph.D. and Preceptors Steven Oh, Ph.D. and Mohammad Heidaran, Ph.D. (CBER), 2016*

6. *Eradication of Mycobacterium chimaera Biofilms Using Cathodic Voltage Controlled Electrical Stimulation in Combination with Antimicrobial Agents,* Fellow Archana Siddam, Ph.D. and Preceptor Jayaleka Amarasinghe, Ph.D. (ORA), 2017

7. *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

8. *Identifying molds and yeasts using matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF MS)*, Fellow: Stephanie Cole, Ph.D. and Preceptor Christine Karbiwnyk, Ph.D. (ORA), 2016

9. *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

10. *Proteomic Characterization of Multipotent Stromal Cells Seeded on Different Scaffolds to Uncover Osteogenic Differentiation Biomarkers,* Fellow Kristin Schultz-Kuszak, Ph.D. and Preceptor Michail Alterman, Ph.D. (CBER), 2011

11. *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

12. *Stability Study of Abuse Deterrent Formulation (ADF) of Opioids to Enhance Assurance of AD Properties During Product Shelf Life*, Fellow Golam Kibria, Ph.D. and Preceptors: Celia Cruz, Ph.D. and Sau (Larry) Lee, Ph.D. (CDER), 2017

13. *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

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. *Development of a Serotyping Pipeline using Whole Genome Sequencing (WGS) for Shigella identification,* Fellow Yun Wu, Ph.D. and Preceptor Henry Lau, Ph.D. (ORA), 2017

6. *Improving Radiological Health for Dental X-ray Imaging- Premarket and Outreach-level Activities,* Fellow Smita Kakar, Ph.D. and Preceptor David C. Spelic, Ph.D. (CDRH), 2017

7. *Likelihood Ratio Test (LRT) for Safety Signal Detections in Clinical Trials*, Fellow Yueqin Zhao, Ph.D. and Preceptor Ram Tiwari, Ph.D. (CDER), 2012

8. *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

9. *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

10. *Sequencing Mycobacterial Strains Isolated from Tattoo Inks*, Fellow Silvia Secelean, Ph.D. and Preceptor Donna Williams-Hill, Ph.D. (ORA), 2014

11. *Streamlining Tobacco Industry Submissions to the FDA Center for Tobacco Products*, Fellow Krystl Haerian, M.D. and Ii-Lun Chen, M.D. and Wendy Aaronson, M.S. (CTP), 2012

12. *Using Decision Analysis tools to advance regulatory science*, Fellow John Kosowicz, Ph.D. and Preceptor Adam Saltman, Ph.D. (CDRH), 2017

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. *Development and Application of High-Resolution Mass Spectrometry (HRMS) Methods to Monitor Veterinary Drugs in Food*, Fellow I-Lu Wu, Ph.D. and Preceptor Sherri B. Turnipseed, Ph.D. (ORA), 2016

3. *Development of Guidelines and Policies for Microbiological Analysis Methods in Cosmetic Products*, Fellow Mi Sun Moon, Ph.D. and Preceptor Nakissa Sadrieh, Ph.D. (CFSAN), 2016

4. *Developing a Universal Enrichment Broth for Foodborne Bacterial Pathogens*, Fellow Kirsten Hirneisen, Ph.D. and Donna Williams-Hill, Ph.D. (ORA), 2012

5. *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

6. *Development and validation of environmental testing methods for Listeria monocytogenes (L. monocytogenes),* Fellow Fengmin Li, Ph.D. and Preceptor Yi Chen (CFSAN), 2016

7. *Development of a Liquid Mid-Density Micro Array Assay for the Detection of Food-Borne Enteric Viruses using Luminex® xMAPTM Technology,* Fellow Subrat Rout, Ph.D. and Preceptor Gary Hartman, M.A. (ORA), 2011

8. *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

9. *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

10. *Evaluation of incompatibility group IncFIB plasmid-mediated virulence in Salmonella enterica,* Fellow: Bijay Khajanchi, Ph.D. and Preceptor Steven Foley, Ph.D., (NCTR), 2015

11. *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

12. *Method development for rapid detection of Cronobacter sakazakii,* Fellow Katie Swensen-Segars, Ph.D. and Preceptor Irshad Sulaiman, Ph.D. (ORA), 2013

13. *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

14. *Rapid Molecular Typing of Shiga Toxin-Producing Escherichia coli Using the Automated DiversiLabÔ 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
15. *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
16. *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
17. *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
18. *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
19. *Validation of a universal broth for multi-pathogen enrichment from environmental swab samples*, Fellow Ashley Queen, Ph.D. and Preceptor Donna-William-Hill, Ph.D. (ORA), 2016

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

Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products

1. *Adolescent use of tobacco and subsequent nicotine dependence*, Fellow Rachel Zamoiski, Ph.D. and Preceptor Nicole Borek, Ph.D. (CTP), 2016
2. *Decision-making model for Wiskott-Aldrich Syndrome*, Fellow Ihid Carniero Lea, Ph.D. and Preceptors Robert Sokilic. Ph.D. and Ke Liu, Ph.D. (CBER), 2016

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 Kilili, 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. *Assessment of Significant Contributors for Quality Deficiency and Review Efficiency of ANDA Process,* Fellow Gloria (Rong) Fu, Ph.D. and Preceptor CAPT Jason Woo, M.D., MPH, FACOG, (CDER), 2017

5. Comparison of Salmonella WGS serotyping methods with bead-based molecular serotyping methods in Salmonella isolated from food and environmental samples, Fellow Kayleigh MacMaster, Ph.D. and Preceptor Michelle Moore, Ph.D. (ORA), 2016

6. *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

7. *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

8. *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

9. *Detection of Shiga Toxin-Producing Escherichia coli,* Fellow Laurie M. Clotilde, Ph.D. and Preceptor Andrew Lin, Ph.D. (ORA), 2011

10. *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

11. *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

12. *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

13. *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

14. *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

15. *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

16. *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

17. *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 Jacquline AM Yancy, Ph.D. and Preceptors Elizabeth Mansfield, Ph.D. and Katherine M. Serrano, B.S. (CDRH), 2011

18. *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

19. *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

20. *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
21. *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
22. *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
23. *Evaluation of next-generation sequencing for quantifying somatic mutations as breast cancer biomarkers*, Fellow Vijay Walia and Preceptor Barbara Parsons, Ph.D. (NCTR), 2016
24. *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
25. *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
26. *FDA Standards Activities in Regenerative Medicine: Enhancing Product Development and Regulatory Review,* Fellow Bao Ngyuen, Ph.D. and Preceptors Carolyn Yong, Ph.D. and Steven Oh, Ph.D. (CBER), 2017
27. *Guidance Development for Future Medical Devices,* Fellow Anh Nguyen, M.D., MBA and Preceptor Markham Luke, M.D., Ph.D. (CDRH), 2011
28. *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
29. *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

30. *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

31. *Physiochemical Characterization of Lipid-based Nano-Drug Complexes*, Fellow Desiree Van Haute, Ph.D. and Preceptor Thilak Mudalige, Ph.D. (ORA), 2016

32. *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

33. *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

34. *Review Approaches for Iterative Development of Regenerative Medicine Products*, Fellow Zehra Tosun and Preceptors Becky Robinson, Ph.D. and Carolyn Yong, Ph.D. (CBER), 2016

35. *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

36. *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