FDA Food and Drug Administration

COMMISSIONER'S

Fellowship Program

Protecting Public Health
Through Science and Regulation

FDA MISSION

The FDA is responsible for protecting the public health by assuring 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. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

For more information on the FDA, visit www.fda.gov.

"What appealed to me most about the fellowship program was the opportunity to learn about regulatory science and participate in public health initiatives for children. As a pediatrician, I came from the clinical side of healthcare and was eager to apply my experience to the broader public health arena."

Francesca Dolcimascolo, M.D.
Class of 2008

PROGRAM OVERVIEW

The two-year Commissioner's Fellowship Program provides an opportunity for health professionals and scientists to receive training and experience at the FDA. Fellows will train at FDA's White Oak campus in Silver Spring, Maryland or at other FDA facilities.

The objective of the Commissioner's Fellowship Program is to train a cadre of highly accomplished scientists intensively in FDA regulatory science across devices, drugs, biologics, foods, tobacco, and cosmetics. In addition to classes in each FDA product area, Fellows will receive instruction in FDA law, policy and international activities, federal budget process, networking and leadership skills, communications with the public and press, biostatistics, epidemiology, clinical trial design, risk assessment and risk management, and extensive case-based learning classes.

In parallel with this didactic training, the Fellows, with the guidance of their senior scientist Preceptor, will engage in a carefully designed and articulated FDA regulatory science project. All FDA Centers, the Office of the Commissioner, and the Office of Regulatory Affairs have identified specific mission-critical research projects, which are posted on the Commissioner's Fellowship Program website. As part of the application process, applicants must identify projects of interest. Research projects are assigned to Fellows after an interview period with potential Preceptors. Each year new projects will be posted.

The FDA expects to retain many Fellows from each class, however, there are no guaranteed positions. Fellows not remaining with the FDA will be well-qualified for employment in industry or academia where the knowledge and perspective they gained at FDA will prove invaluable.

COURSEWORK OVERVIEW*

The Commissioner's Fellowship Program combines graduate-level coursework designed to provide an in-depth understanding of regulatory science.**

Year 1

Semester 1 (October – January)

The first semester presents several short introductory courses that examine core FDA functions. Fellows will spend about 20 percent of their scheduled time completing these courses.

Coursework

1. FDA History and Alumni Perspectives and Key Issues Facing the FDA
2. FDA Policy and Regulatory Processes
3. FOI Overview
4. Beyond Our Borders
5. Office of the Commissioner Overview (OC)
6. Center for Veterinary Medicine Overview (CVM)
7. Center for Devices and Radiological Health Overview (CDRH)
8. National Center for Toxicological Research Overview (NCTR)
9. Center for Biologics Evaluation and Research Overview (CBER)
10. Center for Drug Evaluation and Research Overview (CDER)
11. Center for Food Safety and Applied Nutrition Overview (CFSAN)
12. Office of Regulatory Affairs Overview (ORA)
13. Center for Tobacco Products Overview (CTP)

Research

During this semester each Fellow will work with his or her Preceptor to develop a written research proposal that includes detailed literature review, methods to be used, anticipated outcomes, and skills and techniques to be acquired. Work on the project can begin, even as the formal proposal is developed.

Semester 2 (February – May)

Coursework

1. Fundamentals of Epidemiology

Research

Students will spend about 15 percent of their scheduled time focusing on graduate-level coursework.

"The Commissioner's Fellowship program creates a unique environment which allows for the development of crucial skills and acquisition of pertinent knowledge that, in turn, guides our understanding and appreciation of the intricacies of FDA regulatory science and its relationship to protecting public health."

Uros V. Djekic, Ph.D.
Class of 2008

"The Commissioner's Fellowship Program provides broad exposure to many aspects of regulatory science, while still affording me significant time to pursue my research interests in bioethics. It's a combination that I don't think I could get elsewhere."

John Rossi, V.M.D., M.Be.
Class of 2008

"The agency sees us as valuable assets and a gateway to its success."

Juandria V. Williams, Ph.D.
Class of 2008

Summer Session 1 (June – September)

Coursework

1. Biotechnology: Management of Drug Discovery
2. Budgets, Operations, and Planning

Research

Approximately 85 percent of the Fellows' scheduled time will be spent on their research project. Fellows will give formal presentations to the Fellowship Committee, other Fellows, and Preceptors addressing the public health impacts of their projects.

Year 2

Semester 3 (October – January)

Coursework

1. Introduction to Clinical Trials
2. Topics in Clinical Trials

Research

Students will spend about 15 percent of their scheduled time focusing on graduate-level coursework.

Semester 4 (February – May)

Coursework

1. Clinical Pharmacology/Pharmacokinetics
2. Introduction to Toxicology
3. Risk Management/Risk Assessment

Research

Fellows will spend 90 percent of their scheduled time conducting research relevant to their research projects.

Summer Session 2 (June – October)

The Fellowship ends in October with final presentations of research results to Preceptors, Fellows, and Center staff. In the months leading up to the final presentations, Fellows are expected to focus on finalizing their projects.

* *Please note that all courses will be taught at the White Oak Campus in Silver Spring, Maryland. Remote access will be provided for Fellows at remote FDA locations.*

** *The courses that are instructed at the graduate-level may require commitment outside of the traditional work schedule.*

WHO IS ELIGIBLE TO APPLY?

Applicants must have a Doctoral level degree (M.D., D.O., D.V.M., D.D.S., D.P.M., Pharm.D., or Ph.D.) to be eligible. Applicants with a Bachelor's degree in an engineering discipline will also be considered. Applicants must be U.S. citizens, non-citizen nationals of the U.S., or have been admitted to the U.S. for permanent residence at the time their applications are submitted. Applicants cannot be current FDA employees or FDA contractors (such as ORISE fellows). Applicants must have received their doctoral degree within 7 years of the start date. Applicants who have a Bachelor's or Master's degree in an engineering discipline may also apply, and applicants must have received their degree within 7 years of the start date. NOTE: All degree requirements (including thesis defense) must be complete before the program start date.

HOW DO I APPLY?

Please visit the FDA Commissioner's Fellowship Program website: http://www.fda.gov/CommissionersFellowshipProgram.

WHAT SALARY AND BENEFITS CAN I EXPECT?

Salaries are competitive and commensurate with education and experience. Additional funds are provided for education, travel, and research project expenses.

Fellows are hired as FDA employees, and therefore are eligible for all Federal employee benefits, including health insurance, retirement, and paid vacation. For more information on benefits, please visit: http://www.hhs.gov/careers/pay/index.html.

As an FDA employee, Fellows will be subject to all of the Agency's conflict of interest and ethics rules.

QUESTIONS OR COMMENTS?

Email us at: fdacommissionersfellows@fda.hhs.gov

"The Commissioner's Fellowship provides a hands-on approach to understanding the inner workings of FDA regulatory science and policy. This invaluable experience allows me to gain specific knowledge regarding the protection of human subjects in international clinical trials."

Lester "Jao" Lacorte, M.D.
Class of 2008

"I am very appreciative of the congenial and encouraging work environment where I can share my thoughts and contribute to the team effort."

Paramjeet Kaur, Ph.D.
Class of 2008

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