

**Opportunity Title:** FDA Strategic Partnerships in Regulatory Science Fellowship **Opportunity Reference Code:** FDA-CDER-2019-0447

Organization U.S. Food and Drug Administration (FDA)

#### Reference Code FDA-CDER-2019-0447

How to Apply A complete application consists of:

- An application
- Transcripts Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

All documents must be in English or include an official English translation.

If you have questions, send an email to <u>ORISE.FDA.CDER@orau.org</u>. Please include the reference code for this opportunity in your email.

## Application Deadline 3/31/2020 3:00:00 PM Eastern Time Zone

## Description \*Applications will be reviewed on a rolling-basis.

A research opportunity is available in the Office of Translational Sciences/Immediate Office, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project located in The Office of Translational Sciences / Immediate Office involves collaborating with CDER staff on projects involving the assessment of FDA's regulatory science activities and outreach efforts in Science Technology Engineering and Mathematics (STEM). The project involves various mechanisms available to FDA for partnering with external organizations to promote regulatory science and innovation in drug development, including Technology Transfer, Critical Path Innovation Meetings, Public Private Partnerships and Consortia Activities. This project will have a significant impact on improving strategies and processes for collaborations between CDER and external groups.

Under the guidance of a mentor the participant will learn the mechanisms available to FDA for partnering with external organizations to promote regulatory science and innovation in drug development, assess partnership needs, and participate in identifying the impact of scientific collaborations on CDER's research priorities. This training is critical to our public health mission and will prepare the participant for a successful career transition into regulatory science research.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of

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### the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The qualified candidate should be currently pursuing or have received a bachelor's, master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Familiarity with maintaining and creating databases is desired.

## Eligibility Requirements

- Degree: Bachelor's Degree, Master's Degree, or Doctoral Degree
  received within the last 60 months or currently pursuing.
  - Discipline(s):
    - Communications and Graphics Design (2. (2)
    - Computer, Information, and Data Sciences (16 )

    - Life Health and Medical Sciences (45.)
    - Mathematics and Statistics (1. )
    - Social and Behavioral Sciences (1. )