Opportunity Title: FDA Generic Drug User Fee Amendments (GDUFA) Research Tracking Fellowship
Opportunity Reference Code: FDA-CDER-2019-0441

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

Reference Code FDA-CDER-2019-0441

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 ORISE.FDA.CDER@orau.org. 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 Generic Drugs/Office of Research and Standards, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project in The Office of Research and Standards/ Office of Generic Drugs will research the proper evaluation and approval of generic drugs. The project will support projects for all therapeutic categories of generic drugs and will encompass projects from in vitro to in vivo studies. Results will support development of guidance's, recommendations to Industry, and regulatory review. The project will be focused on the following topic areas: (1) complex active ingredients, formulations or dosage forms, (2) complex routes of delivery, (3) complex drug-device combinations, (4) tools and methodologies for bioequivalence and substitutability evaluation.

Under the guidance of a mentor the participant will be trained in analysis and development of an existing web-based system utilized to maintain tracking and reporting of Generic Drug User Fee Amendments regulatory science projects. The participant will be involved with a range of software development, data management and automated report generation of data and activities related to research projects. 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

Opportunity Title: FDA Generic Drug User Fee Amendments (GDUFA) Research Tracking Fellowship
Opportunity Reference Code: FDA-CDER-2019-0441

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 degree in one of the relevant fields, with a focus on software engineering and a passion for producing quality software. Degree must have been received within five years of the appointment start date.

Familiarity with one or more of the following is desired:

- database design and developing relational databases
- data entry and curation
- computer programming
- text mining (text analytics)
- quantitative statistics, standardized nomenclatures, and/or other terminologies
- JAVA, C#, .NET, HTML/CSS/JavaScript, PEARL

Eligibility Requirements

- **Degree:** Bachelor's Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (1 👁)