Opportunity Title: FDA Drug Safety Fellowship
Opportunity Reference Code: FDA-CDER-2022-0761

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

Reference Code FDA-CDER-2022-0761

How to Apply

Connect with ORISE...on the GO! Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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

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 5/31/2022 3:00:00 PM Eastern Time Zone

Description

***Applications will be reviewed on a rolling basis.**

An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in the Office of New Drugs/ Immediate Office (IO). This opportunity will be located at the National Center for Toxicological Research (NCTR) in Jefferson, Arkansas. CDER performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

FDA/CDER has recently become aware of a newly recognized class of drug impurities and degradation products that are formed from the drug substance itself (referred to a N-nitroso Drug-Substance-Related Impurities, NDSRIs). Because of the structure of these impurities, many could pose a significant cancer risk to patients using medications that contain them. This project will establish short-term tests for evaluating the cancer risk of NDSRIs, using the methods to develop data on this largely unknown class of compounds to populate FDA's in silico prediction tools to limit health risks from these impurities in drug products.

Under the guidance of the mentor, the participant will learn how science can be used to address a major regulatory issue for CDER. The participant will plan, execute, and interpret research that will develop an optimized approach for evaluating the potential cancer health risks associated with a newly recognized class of drug impurities and degradation products.

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

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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 Jefferson, Arkansas, 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 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 have received a bachelor's, master's or doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred skills:

- Basic computer skills (e.g., word processing, spreadsheets)
- Knowledge conducting laboratory research independently, practicing aseptic technique, making solutions, keeping a lab notebook, conducting simple statistical tests, and writing up and presenting data

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (8 👁)

Affirmation

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)