Opportunity Title: FDA Fellowship on Examination of Bioequivalence in Approved Generic Drug Applications
Opportunity Reference Code: FDA-CDER-2022-1212

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

Reference Code FDA-CDER-2022-1212

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 3/31/2023 3:00:00 PM Eastern Time Zone

Description

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

The Center for Drug Evaluation and Research (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 U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

The project in the Office of Bioequivalence (OB), Office of Generic Drugs (OGD) will evaluate the potential impact of outsourcing bioequivalence (BE) studies to non-US based clinical bioresearch monitoring (BIMO) sites and contract research organizations (CROs) on submission quality, data completeness, BE assessment time, and review cycles to achieve BE adequacy.

Under the guidance of the mentor, the participant will learn where OGD fits in the FDA/CDER organization; become familiar with the regulatory framework for generic drugs; and understand potential impacts of outsourcing BE studies to non-US based clinical sites and CROs on submission quality, data completeness and review cycles to achieve timely approval of generic drugs. The participant will learn how to source data using available in-house databases and perform extensive quantitative and qualitative analysis to prepare a final report for presentation.

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

Opportunity Title: FDA Fellowship on Examination of Bioequivalence in Approved Generic Drug Applications
Opportunity Reference Code: FDA-CDER-2022-1212

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 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 master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Qualified bachelor's will be considered provided that the candidate demonstrates strong analytical experience.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Engineering** (2 👁)
  - **Life Health and Medical Sciences** (3 👁)
  - **Mathematics and Statistics** (1 👁)

Affirmation

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