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Opportunity Title: FDA Product Specific Guidance and Research Fellowship
Opportunity Reference Code: FDA-CDER-2024-1375

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

Reference Code FDA-CDER-2024-1375

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 3/29/2024 11:59:00 PM Eastern Time Zone

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

A research opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs/ Office of Research and Standards, Immediate Office located in Silver Spring, Maryland. CDER performs an essential public health task by ensuring safe and effective drugs are available to improve the health of people in the United States population. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than drug products and corresponding regulations.

This project explores knowledge management systems for FDA-funded scientific research, CDER approved drug products, CDER published guidance including product-specific guidance (PSG), as well as the refinement of processes and infrastructure to analyze and track how research outcomes from FDA-funded scientific research can be used to support PSG development. This project includes the development of knowledge management and research management tools to maintain, monitor, and analyze how the impact of outcomes from a scientific research program can be maximized to support future decision making.

The participant will gain insight into the FDA's Office of Generic Drugs, and how their research supports guidance development and regulatory decision making, as part of the Generic Drug User Fee Amendments (GDUFA) Program.

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.

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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 Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

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, PharmD or Doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred candidates will have a demonstrated strong background in written and oral communication.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Communications and Graphics Design** (1 👁)
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (46 👁)
  - **Mathematics and Statistics** (10 👁)
  - **Physics** (16 👁)
  - **Science & Engineering-related** (1 👁)

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- **Social and Behavioral Sciences** (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.)

AND

I have read the FDA Ethics Requirements.