Opportunity Title: FDA Drug Safety - Medication Errors Fellowship
Opportunity Reference Code: FDA-CDER-2024-1392

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

Reference Code FDA-CDER-2024-1392

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 6/28/2024 3:00:00 PM Eastern Time Zone

Description

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

This project is in the Office of Medication Error Prevention and Risk Management (OMEPRM), Office of Surveillance and Epidemiology (OSE). As part of the FDA, DMEPA I & II review and are the regulatory signatures for proprietary names for CDER regulated drug products. DMEPA I & II also spend resources tracking Pending Name Conflicts (PNCs) as a part of our proprietary name program, and industry stakeholders are interested in the success/performance of our PNC tracking on if Applicants end up with their preferred proprietary names. This project will provide a longitudinal look since 2016 to identify PNC metrics and assess DMEPA's PNC part of the name program.

Under the guidance of the mentor formal training will be provided at the Institute for Safe Medication Practices (ISMP) and FDA where the participant will gain knowledge in Root Cause Analysis (RCA), Failure Mode and Effects Analysis (FMEA), and other risk-assessment tools and methods. The research project will provide experience on identifying name confusion errors, become familiar with the regulatory name review process, and regulatory interaction with stakeholders. The participant will develop the specific research methodology, analyze the research findings, and apply the findings to regulatory review.

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 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 have received a master's or doctorate in one of the relevant fields. Degree must have been received within the past five years or be currently pursuing.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.

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- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

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.)

I have read the FDA Ethics Requirements.