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Opportunity Title: FDA Fellowship on Available Methods and Potential Signal Detection in the Biological Product Deviation Report (BPDR)
Opportunity Reference Code: FDA-CDER-2023-1316A

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

Reference Code FDA-CDER-2023-1316A

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 12/29/2023 3:00:00 PM Eastern Time Zone

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

CDER Office/Lab and Location: A research opportunity is available in the Office of Quality Surveillance (OQS), Office of Pharmaceutical Quality (OPQ), Food and Drug Administration (FDA) located in Silver Spring, Maryland. This is a collaborative research project in the Center for Drug Evaluation and Research (CDER).

Research Project: The project includes understanding manufacturing deviations submitted in Biological Product Deviation Report (BPDR) for CDER-regulated biologics drugs using CDER BPDR management database and tools. The current BPDR management process will be explored for any ideas on potential improvements. The focus of the project will be to research different methodologies to identify and compile clusters and/or trends for potential product quality signals.

Under the guidance of the mentor, the participant will be able to explore CDER BPDR program and understand the process on how these reports are handled. The participant will learn basic concepts of biologics manufacturing process and CGMP practices in this research project and will participate in real case studies.

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.

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

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interagency agreement between DOE and FDA. The appointment is for 12 months. 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 part-time or full-time at FDA in the Silver Spring, Maryland or St. Louis, Missouri areas. 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 bachelor's, master's, or doctoral degree in one of the relevant fields, received within the last 60 months, or be currently pursuing their degree.

Preferred skills/knowledge:

- Basic knowledge in pharmaceutical manufacturing process and CGMP compliance

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (48 👁)

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.