Opportunity Title: FDA Data Mining of IND and NDA Submissions Fellowship
Opportunity Reference Code: FDA-CDER-2022-0796

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

Reference Code FDA-CDER-2022-0796

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 12/31/2022 3:00:00 PM Eastern Time Zone

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

A research opportunity is available with the Office of Pharmaceutical Quality (OPQ)/ Office of New Drug Products (ONDP) in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. 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.

This project will serve to better understand the unique chemistry, manufacturing, and controls (CMC) challenges associated with 505(b2) submissions through data-mining deficiencies identified during 505(b2) assessment. A 505(b2) application is a new drug application (NDA) described in section 505(b2) of the Federal Food, Drug, and Cosmetic Act. A 505(b2) NDA is an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

The goal of the project is to understand the unique CMC challenges associated with 505(b2) submissions through data-mining deficiencies identified during 505(b2) CMC assessment, conduct root cause investigations and propose mitigation plans to address common deficiencies. By doing that, OPQ/ONDP could provide general advice to sponsors/applicants at earlier development stages to address common deficiencies. This could lead to more efficient drug development and more first cycle approvals of 505(b2) applications with less agency inquiries during the review cycle.

Under the guidance of a mentor, the participant will conduct data mining of investigational new drug applications (IND) and NDA submissions. The participant will learn current regulations, policy, and guidance related to different types of drug applications from a CMC perspective. Furthermore, the participant will learn about the pharmaceutical development process from a regulatory perspective. The participant will also learn about appropriate CMC review strategies for INDs and

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NDAs.

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 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, or be currently pursuing one of the degrees with completion by the end of June 2022. Degree must have been received within five years of the appointment start date.

Preferred Skills/ Knowledge:

- Knowledge with searching within files and databases (manually and using SQL)
- Knowledge in data management and automation processes, including data standardization, transformation, validation, loading and analyses
- Skills with database and information management programs such as Microsoft Access, SQL Server, and SharePoint

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2022 12:00:00 AM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Computer, Information, and Data Sciences** (3 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (48 👁)

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.)

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