

Opportunity Title: FDA Knowledge Management Database Fellowship

Opportunity Reference Code: FDA-CDER-2022-0754

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

Reference Code FDA-CDER-2022-0754

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

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

An 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 Bioequivalence (OB) in Silver Spring, Maryland.

The Office of Bioequivalence relies upon a multitude of scientific databases to assess the acceptability of a generic drug application. The current process requires reviewers to individually search the databases and synthesize the information. Due to the challenges of processing disparate sources of information, the assessment of a review can vary among reviewers. This in turn can lead to additional review cycles, unnecessary deficiencies, and increased number of meetings, and can limit the ability to use past experience to make a decision. The aim of the project is to develop a "one stop shop" database that will unify the different databases.

Under the guidance of the mentor, the participant will learn the concepts and principles of bioequivalence, pharmacokinetics, and pharmacodynamics. The participant will also learn about making a knowledge management database which enables an assessment of an application using all available knowledge. The participant will learn about the regulations and guidance underlying the review and assessment of generic drug applications.

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



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

Preferred skills:

- Demonstrated strong biomedical/biochemical experiences
- Knowledge in database creation and management

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** (3 )
 - **Computer, Information, and Data Sciences** (17 )
 - **Engineering** (1 )
 - **Environmental and Marine Sciences** (1 )
 - **Life Health and Medical Sciences** (17 )
 - **Mathematics and Statistics** (6 )

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.)