

Opportunity Title: FDA Fellowship in Clinical, PK, and CMC Conditions Needed to Support the Extended-Release Claim of a Drug Product

Opportunity Reference Code: FDA-CDER-2023-1235

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

Reference Code FDA-CDER-2023-1235

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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 3/31/2023 3:00:00 PM Eastern Time Zone

Description The project in the Office of New Drug Products (ONDP), Office of Pharmaceutical Quality (OPQ), Division of Biopharmaceutics, aims to determine clinical, pharmacokinetic, and Chemistry, Manufacturing, and Control (CMC) conditions that are needed to support an "extended release (ER)" claim for a drug product and the reasons for the denial of ER claims. The project also aims to examine the utility of physiologically-based pharmacokinetic (PBPK) modeling and simulation approaches for biopharmaceutics application as an alternative approach in the absence of adequate in vivo data.

Under the guidance of the mentor, the participant will learn to utilize FDA databases for gathering scientific information and how to analyze the data to draw scientific conclusions. The participant will also learn modeling and simulation methodologies and software for biopharmaceutics 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 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.



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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 Doctoral degree in one of the relevant fields, or be currently pursuing the degree with completion before June 30, 2023. Degree must have been received within five years of the appointment start date.

Preferred skills/ knowledge:

- Strong analytical capability.
- Pharmacy / pharmacology related knowledge is preferred.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2023 11:59:00 PM.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** (1 )
 - **Engineering** (1 )
 - **Life Health and Medical Sciences** (2 )

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.)