Opportunity Title: FDA Fellowship for Clinical Pharmacology Modeling and Simulation Faculty Program
Opportunity Reference Code: FDA-CDER-2024-1396

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2024-1396

How to Apply

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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
- A copy of an abstract or reprint of an article

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 4/15/2024 3:00:00 PM Eastern Time Zone

Description

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

CDER Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at Silver Spring, Maryland.

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.

Research Project: This project is in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS). The project will consist of using modeling approach (e.g., physiology-based pharmacokinetic modeling (PBPK) to address clinical pharmacology and precision medicine issues in pediatric patients, such as predicting the pharmacokinetics of drugs in pediatrics with different ages or body weights. The project will also provide knowledge on regulatory sciences.

Learning Objectives: Under the guidance of the mentor, the participant will learn about regulatory sciences and procedures, including how FDA functions and the process of drug reviews, and how Clinical Pharmacology contributes significantly to drug

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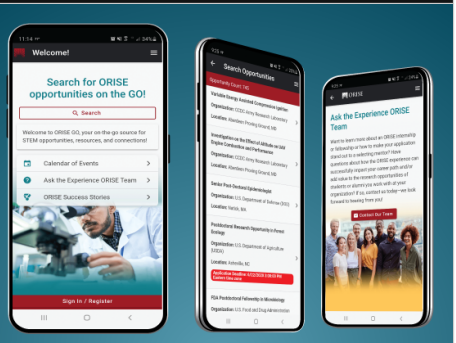

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development and review. The participant will learn how to apply modeling to predict pharmacokinetics of drugs in pediatrics and interact with experts in OCP including experts in clinical pharmacokinetics in pediatrics and experts in PBPK modeling.

Appointment Length: The appointment will initially be for 3 months, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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:

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- 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 hold a current faculty position in a U.S. university and have received a doctoral in one of the relevant fields (Pharmaceutical Sciences).

Preferred experience/skills:

- A strong background in PBPK modeling and knowledge about ontogeny of drug metabolic enzymes and transporters is desirable.

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Academic Level(s):** Postdoctoral.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (1 👁)

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.