Opportunity Title: FDA Postdoctoral Fellowship in Quantitative Systems Pharmacology Modeling
Opportunity Reference Code: FDA-CDER-2023-1284

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

Reference Code FDA-CDER-2023-1284

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 9/30/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS), within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Fellow will be in California participating with our collaborator at University of California San Diego (La Jolla, California).

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.

Assessing drug safety is a challenging aspect of pediatric drug development which stems from the inconsistent results from preclinical safety studies, such as juvenile animal studies, and extrapolated or small clinical safety studies. Innovative nonclinical approaches, such as the proposed quantitative systems pharmacology (QSP) model, are essential to predict and avert major drug adverse events (ADEs) in developing pediatric patients. This project will establish the basis for a QSP model that can red flag drugs intended for pediatric use that may produce long-term adverse safety events to have sponsors perform post-marketing safety studies. This initial QSP model will be constructed by integrating biological and cellular pathways involving bone development followed by neurodevelopment. This is the first step at making a developmental safety model and it will be continually updated to include other pediatric developmental toxicities such as cardiovascular, gastrointestinal, hepatotoxicity, etc.

Under the guidance of the mentor, the participant will be involved in the following activities: (1) learn about model-informed drug development and quantitative systems pharmacology (QSP) modeling, (2) develop a QSP

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bone model based on literature data and go through the calibration and validation steps, (3) perform a literature search related to the background of the project, and (4) present scientific findings at project meetings, poster presentation, and write up a manuscript.

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

Preferred skills/ knowledge:

- Pharmacology knowledge – PharmD or equivalent
- Quantitative modeling or analysis

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**

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- **Chemistry and Materials Sciences** (3 👁)
- **Communications and Graphics Design** (2 👁)
- **Computer, Information, and Data Sciences** (3 👁)
- **Engineering** (1 👁)
- **Environmental and Marine Sciences** (3 👁)
- **Life Health and Medical Sciences** (48 👁)
- **Mathematics and Statistics** (1 👁)
- **Other Non-Science & Engineering** (1 👁)
- **Physics** (1 👁)
- **Science & Engineering-related** (2 👁)
- **Social and Behavioral Sciences** (3 👁)

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.