

Opportunity Title: FDA Postdoctoral Fellowship in Using Modeling and Simulations to Support Bioequivalence

Opportunity Reference Code: FDA-CDER-2023-1293

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

Reference Code FDA-CDER-2023-1293

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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@oraui.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.

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 research covers more than just medicines.

This project is in the Office of Research and Standards (ORS), Office of Generic Drugs (OGD) and will provide an outstanding opportunity to learn and apply population pharmacokinetic and physiologically based pharmacokinetic (PBPK) modeling and simulations to support the bioequivalence (BE) assessment.

Under the guidance of the mentor, the research participant will be involved in investigating and determining appropriate covariates to be included in the statistical model for parallel BE studies; developing and applying PBPK modeling to conduct risk-based BE assessment and support biowaiver. We have established PBPK and popPK models as risk assessment tools for various purpose, which can be used as training models. The participant can establish a PBPK model to evaluate the impact of food and gastric pH on bioequivalence between generic and innovator drugs and use popPK model to assess the impact of adding covariates to the statistical model for the parallel study on the bioequivalence determination.

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



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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. Preferred fields include Pharmaceutical Sciences, Clinical Pharmacology, or Pharmacometrics. Degree must have been received within five years of the appointment start date.

- Eligibility Requirements**
- **Degree:** Doctoral Degree received within the last 60 month(s).
 - **Discipline(s):**
 - **Life Health and Medical Sciences** ([48](#)👁)
 - **Mathematics and Statistics** ([11](#)👁)

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.)

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and

I have read the FDA Ethics Requirements.