Opportunity Title: FDA Clinical Pharmacology Fellowship
Opportunity Reference Code: FDA-CDER-2023-1331

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

Reference Code FDA-CDER-2023-1331

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 12/29/2023 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 Therapeutic Biologics and Biosimilars (OTBB) / Office of New Drugs (OND) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), located in Silver Spring, Maryland.

The project will support data analysis necessary to address FDA's and stakeholders' scientific questions relative to biosimilar product development and regulations. Findings from this research will be used to create internal scientific policies and to provide advice and recommendations for product-specific biosimilar development programs and planned revisions to clinical pharmacology biosimilar guidance document. The proposed project will specifically focus on evaluating the potential of using the truncated area under the concentration curve as the primary pharmacokinetic endpoint for comparability assessment in therapeutic biological products (including biosimilars), especially monoclonal antibodies with long half-lives. The project will evaluate the use of receptor occupancy as a pharmacodynamic (PD) endpoint for biosimilar development of biologics, with an initial focus on omalizumab as a model.

Under the guidance of the mentor, the participant will perform research and analysis of publicly available information and FDA in-house data, producing results used by regulatory scientists as background data for decision making.

Anticipated Start Date: The start date is flexible and will depend upon a variety of factors.

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 or be currently pursuing a Bachelor's, Master's or Doctoral degree in one of the relevant fields. Qualified Master's and Bachelor's level degrees may also be considered provided that the candidate demonstrates strong analytical experience. Degree must have been received within the past five years.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (1 👁)
  - **Mathematics and Statistics** (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.)

I have read the FDA Ethics Requirements.