Opportunity Title: FDA Understanding the Challenges in IVIVC Evaluation Fellowship
Opportunity Reference Code: FDA-CDER-2022-0808

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

Reference Code FDA-CDER-2022-0808

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 10/31/2022 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 Pharmaceutical Quality (OPQ)/ Office of New Drug Products (ONDP) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. 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.

This project in OPQ/ONDP will help both the FDA and the selected participant to better understand the challenges in *in vitro in vivo* correlation (IVIVC) development from methodological perspectives and provide the best practices of IVIVC development and evaluation based on FDA review and research experiences. Developing IVIVCs for solid oral dosage forms, especially for extended release (ER) formulations, has been encouraged by regulatory agencies with the expectation that a successful IVIVC will permit certain formulation and manufacturing changes without an in vivo bioequivalence study and for establishing dissolution specifications supported by the model.

The participant will learn to conduct relevant literature and regulatory database searches and perform meta-analysis of submitted IVIVC submissions (failed, approved, and in progress reviews). This will help to improve the understanding of development of successful IVIVC models. The participant will also learn the basics of drug product development and the role of FDA in regulating drug product quality, policy, and guidance.

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

Opportunity Title: FDA Understanding the Challenges in IVIVC Evaluation Fellowship
Opportunity Reference Code: FDA-CDER-2022-0808

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 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 bachelor's, master's, or doctoral (preferred) degree in one of the relevant fields, or be currently pursuing one of the degrees with completion by the appointment start date. Degree must have been received within the past five years.

Qualified bachelor's and master's level candidates will be considered provided that the candidate demonstrates modeling knowledge.

Preferred Skills:

- Physiological-Based Modeling knowledge with formulation background
- Modeling software skills in R, Phoenix, GastroPlus, Nonmem, and/or Symcyp
- Knowledge in clinical pharmacology and pharmacokinetics

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Mathematics and Statistics** (11 👁)

Affirmation

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive)