Opportunity Title: FDA Development of In Vitro Dissolution Methods for Potential Risk-based Biowaivers
Opportunity Reference Code: FDA-CDER-2023-1266

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

Reference Code FDA-CDER-2023-1266

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 11/3/2023 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 Testing and Research (OTR), Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in St. Louis, Missouri. 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 is about risk assessment for IR solid oral products (BCS Class 2a) that aims to develop bio predictive in vitro dissolution methods and evaluate biowaiver extension potential for these drug products. The developed in vitro methods may explore correlations that exist between the critical material attributes and process parameters, and the in vivo performance of the drug product. Therefore, the dissolution methods may be considered discriminating with regard to rejecting batches that are not bioequivalent to batches used in pivotal clinical trials.

Under the guidance of the mentor, the participant will evaluate the performance parameters and physicochemical properties of the drug substance and drug product. The participant will gain a comprehensive understanding of the scientific and regulatory challenges that must be considered during application review and may gain knowledge in collaborating with cross-disciplinary teams on in vivo, and/or in silico study designs. The participant will learn and be able to improve skills on in vitro performance testing of drug products with USP methods, as well as novel physiologically relevant methods.

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-

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time at FDA in the St. Louis, Missouri, 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 master's or doctoral degree in one of the relevant fields, or be currently pursuing one of the degrees with completion by November 3, 2023. Degree must have been received within the past five years.

Preferred knowledge/skills:

- Experience in analytical chemistry and pharmaceutical science are preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 11/3/2023 11:59:59 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (2 👁)
  - **Engineering** (2 👁)
  - **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.)

AND

I have read the FDA Ethics Requirements.