Opportunity Title: FDA Bioequivalence of Complex Generic Products Fellowship
Opportunity Reference Code: FDA-CDER-2022-0791

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

Reference Code FDA-CDER-2022-0791

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 12/31/2022 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 Generic Drugs/Office of Research and Standards (ORS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

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 work covers more than just medicines.

This research project is related to topical, transdermal and transmucosal products to understand the formulations that have been approved under abbreviated new drug applications (ANDAs) and NDAs. The project will also identify and develop in vitro, in vivo, or in silico techniques that may be capable of determining how various complexity factors can impact the bioequivalence of test products to their respective reference product and identifying potential scientific gaps in the application of novel technologies for characterizing the bioequivalence of complex generic products.

Under the guidance of the mentor, the participant will gain a comprehensive understanding of the scientific and regulatory challenges that must be considered when establishing bioequivalence for complex generic topical, transdermal and

Opportunity Title: FDA Bioequivalence of Complex Generic Products Fellowship
Opportunity Reference Code: FDA-CDER-2022-0791

transmucosal drug products including combination drug-device products with device components that may themselves have degrees of complexity in design. In addition, the participant will gain knowledge in collaborating with cross-disciplinary teams to develop novel in vitro, in vivo, and/or in silico study designs for establishing bioequivalence with these products.

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 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 master's or doctoral degree in one of the relevant fields (e.g. pharmaceutical science, pharmacology, pharmacy, or a related area). Degree must have been received within the last 5 years.

Preferred skills:

- Drug development research or pharmaceutical industry knowledge
- Familiarity with formulation development and characterization of drug products and analytical techniques

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.

Opportunity Title: FDA Bioequivalence of Complex Generic Products Fellowship
Opportunity Reference Code: FDA-CDER-2022-0791

- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (1 👁)

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.)