zintellect
climb higher

Opportunity Title: FDA Characterization of Drug Product in Soft Food Fellowship
Opportunity Reference Code: FDA-CDER-2021-0711

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

Reference Code FDA-CDER-2021-0711

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
- Two educational or professional recommendations

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 1/31/2022 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) 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.

Dysphagia affects approximately 15 million U.S. adults per year causing difficulty in swallowing tablets or capsules for therapeutic treatment. Some tablet or capsule products allow for co-administration via soft foods to improve compliance. Despite the benefits for dysphagic patients, the vast majority of tablet or capsule products are not formulated or assessed for co-administration via soft food. This study aims to evaluate how different soft food properties may impact product quality, which can inform development of reliable in vitro assessments to characterize co-administration of drug products with soft food.

Under the guidance of the mentor, the participant will learn the regulatory application of pharmaceutical product quality and will learn advanced pharmaceutical characterization techniques and 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-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 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 analytical chemistry, pharmaceutical sciences, pharmacology, health sciences, physical sciences, or a related field, or be currently pursuing the degree with completion by October 1, 2021. Degree must have been received within five years of the appointment start date.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 10/1/2021 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (2 👁)
  - **Life Health and Medical Sciences** (46 👁)

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.)