Opportunity Title: FDA Postdoctoral Fellowship: Manufacturing Therapeutic Proteins and Minimizing Product Quality Risk
Opportunity Reference Code: FDA-CDER-2023-1246

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

Reference Code FDA-CDER-2023-1246

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 3/19/2023 3:00:00 PM Eastern Time Zone

Description

***Applications will be reviewed on a rolling-basis.**

A research opportunity is available at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), located 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 the Office of Pharmaceutical Quality (OPQ), Office of Testing and Research (OTR) seeks to understand manufacturing process risks and their impact to drug product quality to develop or improve quantitative analysis procedures for product quality assessment and prediction. The goal of this research is to evaluate the impact of process variables on pharmaceutical quality of drug products and drug substances including protein active pharmaceutical ingredients (APIs).

Under the guidance of a mentor, the participant will learn to perform experiments encompassing the upstream production process for therapeutic protein drug substances, gain understanding of variables affecting drug product quality, and incorporate advanced process monitoring technologies and methodologies for evaluating the production performance parameters and physicochemical characterization of the drug substance. The participant will learn and be able to improve skills on bioreactor productions, mammalian cell culture, titer quantification, protein characterization and glycan measurements.

Anticipated Start Date: January 2023. The start date is flexible and will depend upon a variety of factors.

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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 a Master's or doctoral degree or be currently pursuing a doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Candidates with knowledge or an aptitude to learn and excel in mammalian cell culture, sterile handling, HPLC and/or FPLC purification techniques are encouraged to apply.

Candidates with experience in Biotechnology are of particular interest for this opportunity and are encouraged to apply.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (2 👁)
  - **Life Health and Medical Sciences** (4 👁)

Affirmation

I have received a Master's or doctoral degree or am currently

pursuing a doctoral degree.

AND

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.)