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Opportunity Title: FDA Bioprocessing Analytical Lab Fellowship
Opportunity Reference Code: FDA-CDER-2023-1263

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

Reference Code FDA-CDER-2023-1263

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 6/30/2023 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 Pharmaceutical Quality (OPQ), Office of Biotechnology Products (OBP) Center for Drug Evaluation and Research (CDER) at the U.S. 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 U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than just medicines.
Drug product quality is impacted by variability in critical quality attributes (CQA), such as high molecular weight species, and particulates of injectable protein therapeutics. The primary objective of this project is to evaluate biosimilar and originator quality metrics in therapeutic protein drugs. A secondary objective of the project is to understand the impact of container closure systems and develop suitable methods to detect and evaluate particulates/particles in therapeutic protein formulations under relevant stress conditions. This project will evaluate potential real-world scenarios which may negatively impact the quality of protein therapeutics (e.g., insulin, monoclonal antibodies) products including biosimilars and develop additional methods for evaluation of particles in biologic drug products.

Under the guidance of the mentor, the participant will gain scientific background and learn regulatory challenges in this area along with knowledge of industry standard instruments in the laboratory. The bioprocessing analytical lab leverages state of the art instrumentation implemented in the biotech industry. This project will likely generate results for publications in peer-reviewed journals, presentations at internal/external forums (posters, talks) for stakeholders including drug and instrument manufacturers.

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 full-time for a year,**

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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 on location 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 be currently pursuing or have received a bachelor's, master's, or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills/knowledge:

- Familiarity in laboratory settings
- Background in Analytical Chemistry involving biologic/protein drug molecules, including High Performance Liquid Chromatography, dynamic light scattering and/or other particle sizing techniques
- Protein characterization

Candidates interested in any of the following subjects are encouraged to apply:

- Formulation and stability of therapeutic protein drugs
- Post market evaluation of therapeutic protein drugs
- Physiochemical characterization of therapeutic protein drugs

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** (4 👁)
  - **Engineering** (3 👁)
  - **Life Health and Medical Sciences** (6 👁)
  - **Science & Engineering-related** (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.)