

Opportunity Title: FDA Protein Biochemistry Fellowship

Opportunity Reference Code: FDA-CDER-2022-0824

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

Reference Code FDA-CDER-2022-0824

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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@oraui.org. Please include the reference code for this opportunity in your email.

Application Deadline 8/8/2022 11:31:05 AM Eastern Time Zone

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

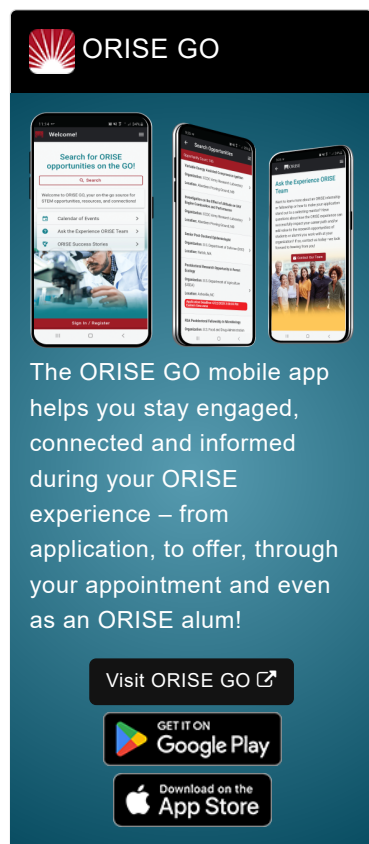
A research opportunity is available in the Office of Pharmaceutical Quality/Office of Biotechnology Products, Center for Drug Evaluation and Research (CDER), Food and Drug Administration in Silver Spring, Maryland.

This project will address how different biological, physical, and chemical factors influence the safety and efficacy of a protein drug. These factors could impact critical product attributes during the manufacture, storage, and/or usage of the drug. One of the major influences on the stability and performance of a protein drug is its formulation. Excipients that are added to stabilize proteins can and do disrupt the safety and efficacy of products, under certain circumstances. A multi-disciplinary approach is critically needed to understand their impact and mechanism in order to understand their realistic clinical impact and make sound regulatory assessments.

Under the guidance of a mentor, the participant will be trained on protein biochemistry and the impact of protein oxidation using *in vitro* and *in vivo* models. Activities may include orthogonal validation experiments utilizing specialized equipment such as mass spectrometry and chromatographic methods to characterize the structure-function relationship between oxidation and drug purity, potency and immunogenicity. This training will prepare the participant for a successful career transition into regulatory science research.


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




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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 master's or doctoral degree in one of the relevant fields, with familiarity of protein biochemistry research areas. Degree must have been received within five years of the appointment start date.

Familiarity with protein purification and mass spectrometry of large proteins is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** ([3](#))
 - **Environmental and Marine Sciences** ([1](#))
 - **Life Health and Medical Sciences** ([45](#))

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.)