

Opportunity Title: FDA-CDER Postdoctoral Fellowship in Biological Product

Quality Research

Opportunity Reference Code: FDA-CDER-2023-1360

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

Reference Code FDA-CDER-2023-1360

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

Application Deadline 3/29/2024 3:00:00 PM Eastern Time Zone

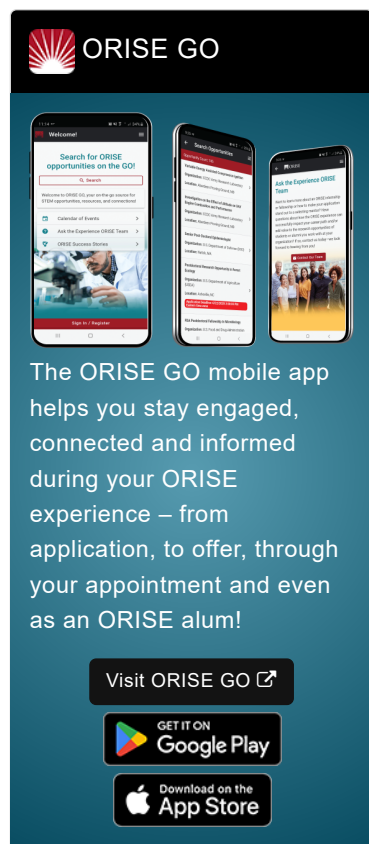
Description *Applications will be reviewed on a rolling-basis.

CDER Office/Lab and Location: A research opportunity is available in the Office of Biotechnology Products (OBP), Office of Pharmaceutical Quality (OPQ) within the Food and Drug Administration (FDA) located 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than just medicines.

Research Project: This project will consist of; advanced manufacturing and analytics for biological product manufacturing and quality, biological assays to support biological product development and testing, assays and models to detect impurities that increase the risk of immunogenicity and support biosimilar and interchangeable product development.

Under the guidance of the mentor, the participant will gain knowledge in the scientific background and regulatory challenges in this area, technical issues, experimental design and research methods. The participant will learn approaches to data analysis and evaluation and have opportunities to communicate scientific data through presentations to peers and/or written communications.

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 appointment is for 12 months. 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.



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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 Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

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

- 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** ([12](#))
 - **Computer, Information, and Data Sciences** ([17](#))
 - **Engineering** ([27](#))
 - **Life Health and Medical Sciences** ([51](#))

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.)

and

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I have read the FDA Ethics Requirements.