

Opportunity Title: FDA Fellowship in Cell Line Development and Bioproduction
Opportunity Reference Code: FDA-CDER-2023-1223

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

Reference Code FDA-CDER-2023-1223

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.

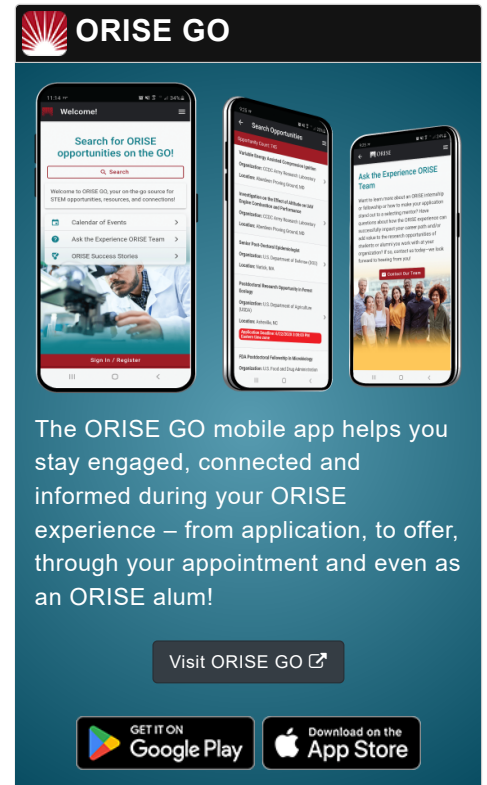
Application Deadline 3/31/2023 3:00:00 PM Eastern Time Zone

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

CDER Office/Lab and Location: The project is the Office of Biotechnology Products (OBP) / Office of Pharmaceutical Quality (OPQ). Cell substrates are cell lines that are used to manufacture therapeutic proteins. During drug product lifecycle management, cell substrates can directly impact product quality. This project focuses on identifying genetic and proteomic factors that associate with changes in the quality of drug products.

Research Project: Under the guidance of the mentor, the participant's research activities include tailored training experiences in different types of scientific techniques which may include: vector construct design, molecular cloning methods, aseptic cultivation, adherent and suspension cell line development, flow cytometry, immunoblotting, DNA electrophoresis, SDS-PAGE, mammalian cell colony selection using Clonepix, ultra-performance liquid chromatography, accelerated protein stability methodology, fast performance liquid chromatography, biolayer interferometry, image capillary isoelectric focusing, capillary SDS-PAGE, gel electrophoresis, and spectrophotometry.

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.



Opportunity Title: FDA Fellowship in Cell Line Development and Bioproduction

Opportunity Reference Code: FDA-CDER-2023-1223

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 bachelor's degree in one of the relevant fields, or be currently pursuing the degree with completion before January 2, 2023. Degree must have been received within five years of the appointment start date.

Preferred skills/ knowledge: Experience in mammalian cell culture in a laboratory environment.

Eligibility Requirements

- **Degree:** Bachelor's Degree received within the last 60 months or anticipated to be received by 1/2/2023 12:59:59 PM.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** (1 )
 - **Life Health and Medical Sciences** (3 )

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.)