Opportunity Title: Summer FDA Fellowship in Assessing Safety and Efficacy of Antibody Therapies
Opportunity Reference Code: FDA-CBER-2024-07

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

Reference Code FDA-CBER-2024-07

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

Description ***Applications will be reviewed on a rolling-basis and this opportunity will remain open until filled.**

A research opportunity is currently available at the Center for Biologics Evaluation and Research (CBER), in the Office of Therapeutic Products(OTP), under the Office Plasma Protein Therapeutics (OTTP), Food and Drug Administration (FDA) in Silver Spring, Maryland.

The research project is focused on developing tissue chips and micro-physiological systems (MPS) that can be used for evaluating safety and efficacy of antibody-based biologic drugs. If selected, the fellow will learn to utilize mammalian cell cultures (such as placenta and other cells) to construct and evaluate tissue chips, incorporate them into MPS using state-of-the-art micro-fluidic platforms, evaluate cellular architecture and function. They are responsible for successfully completing all the institutional training for interacting safely with pathogens and adhering to all the rules and regulations while performing their laboratory activities.

Anticipated Appointment Start Date: June 1, 2024

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 two months, 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 Ethics Requirements

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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 an associates or bachelor's degree in one of the relevant fields.

Preferred skills:

- Interest biomedical and biomaterials research
- College level coursework in STEM fields and associated labs

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Currently pursuing an Associate's Degree or Bachelor's Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (3 👁)
  - **Engineering** (4 👁)
  - **Life Health and Medical Sciences** (9 👁)

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.)

I have read the FDA Ethics Requirements.