Opportunity Title: FDA Fellowship in Understanding the Role and Regulation of Hemostatic Proteins in Patients with Sickle Cell Disease
Opportunity Reference Code: FDA-CBER-2024-0012

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

Reference Code FDA-CBER-2024-0012

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.

Application Deadline 8/30/2024 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: 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.

Research Project: A post-baccalaureate, postmaster or postdoc trainee opportunity in the field of biochemistry and molecular biology is open in the lab of Dr. Chava Kimchi-Sarfaty in the Center for Biologics Evaluation and Research of the FDA. Our lab is broadly interested in understanding the role and regulation of hemostatic proteins and the impact of unbalanced VWF:ADAMTS13 in patients with sickle cell disease (SCD). This is an exceptional opportunity for to learn new analytics skills as part of a collaborative research group.

The successful candidate will collaborate as part of a group that includes biochemists, molecular biologists and computational biologists and collaborate with other research groups. The main research project will consist of multiple, complementary laboratory-based assessments to characterizing VWF and ADAMTS13 in plasma samples obtained from patients, the plasma samples will also be evaluated for targeted biomarkers of SCD disease.

Previous trainees have co-authored peer-reviewed publications, and several have successfully matriculated to graduate or medical school.

Learning Objectives: Under the guidance of a mentor, the participant will gain experience in a range of techniques will be used to address urgent unmet needs related to protein therapeutics.

Anticipated Start Date: May 1, 2024.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

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Citizenship Requirements: This opportunity is available to U.S. citizens and Lawful Permanent Residents (LPR) only.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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

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 have received a bachelor's, master's, or doctoral degree in one of the relevant fields or currently pursuing with an expected graduation date of May 31, 2024.. Degree must have been received within the past five years.

Preferred skills:

- Applicants should have prior hands-on experience in biochemical techniques, experience in handling and processing specimens and cell culture
- Ability to work collaboratively and adopt new technologies outside their comfort zone is an essential quality for this opportunity
- Experience and/or coursework in the fields of biochemistry and molecular biology
- Hands-on experience in biomolecular analysis such as PCR, Western Blotting, ELISA

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or anticipated to be received by

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- **Academic Level(s):** Graduate Students, Post-Bachelor's, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **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.)

I have read the FDA Ethics Requirements.