Opportunity Title: FDA Fellowship on Blood Plasma and Coagulation Factors
Opportunity Reference Code: FDA-CBER-2023-46

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

Reference Code FDA-CBER-2023-46

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
- A cover letter including career goals (upload in the writing sample section)
- One educational or professional recommendations

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 3/31/2024 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available with the Office of Therapeutics Proteins (OTP) at the Center for Biologics Evaluation and Research (CBER), U.S. Food & Drug Administration (FDA) in Silver Spring, Maryland. The successful candidate will conduct experiments on human and mouse blood plasma supplemented with coagulation factor proteins to investigate the mechanisms of coagulation and drug action. The experiments will include enzymatic, clotting, antigen and thrombin generation assays. Mouse models may be used to study drug pharmacokinetics and pharmacodynamics. The candidate will receive mentoring on fulfilling the project, which will also include collaboration with investigators within and external to the FDA. Learning objectives will include training in design of experiments, preparation of scientific manuscripts and reports, presentation of data at scientific meetings, analytical assay development, and application of traditional and investigational clinical laboratory assays.

The following papers provide examples of the research work performed in our group:

1. Parunov LA, Shea ME, Liang Y, Surov SS, Chattopadhyay M, Lee TK, Scott DE, Ovanesov MV. Thrombin generation test based on a 96-channel pipettor for evaluation of FXIa procoagulant activity in pharmaceuticals. Nat Protoc. 2021 Aug;16(8):3981-4003.

2. Liang Y, Tarandovskiy I, Surov SS, Ovanesov MV. Comparative Thrombin Generation in Animal Plasma: Sensitivity to Human Factor XIa and Tissue Factor. Int J Mol Sci. 2023 Aug 18;24(16):12920.

3. Liang Y, Jackson JW, Woodle SA, Surov SS, Parunov LA, Scott DE, Weinstein M, Lee TK, Ovanesov MV. Detecting factor XIa in immune globulin products: Commutability of international reference materials for traditional and global hemostasis assays. Res Pract Thromb Haemost. 2020 Dec 23;5(1):211-222.

4. Jackson JW, Surov SS, Liang Y, Parunov LA, Ovanesov MV. Effect of pH on thrombin activity measured by calibrated automated thrombinography. Res Pract Thromb Haemost. 2020 Jun 12;4(5):944-945.

This position offers training in cutting edge technologies directly relevant to promoting public health, opportunities to attend seminars and formal training programs. The candidate will work on collaborative projects with academia and/or industry and will thus be well positioned for diverse career options after the training period. Flexibility and a willingness to learn new techniques is a desirable quality in the applicant.

Anticipated Appointment Start Date: January 1, 2024; start date is flexible

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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 8 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

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

Applicants must have received a Bachelors, Masters or Doctoral degree in one of the relevant fields, or related disciplines appropriate to the position from a US-accredited institution within five (5) years of the desired starting date. Current students who expect to receive their degree by the desired starting date may apply. Receipt of the degree is required prior to the start of the fellowship.

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PREFERRED SPECIALIZED EXPERIENCE: Skills with laboratory science in the biochemistry and/or biophysics fields are highly desired. Experience with at least one of the following is preferred: hemostasis and thrombosis, protein purification, enzymology, clinical laboratory assays, mouse models of disease, cellular and gene therapy.

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 👁)
  - **Life Health and Medical Sciences** (51 👁)

Affirmation

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)

I expect to receive my degree prior to the start date.

and

I have read the FDA Ethics Requirements.