Opportunity Title: FDA Fellowship in Biochemistry of Blood Coagulation
Opportunity Reference Code: FDA-CBER-2023-14

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

Reference Code FDA-CBER-2023-14

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 12/31/2023 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 in the Office of Tissue and Advanced Therapeutics (OTAT) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This fellowship will be focused on investigating the biochemical mechanisms of human blood coagulation, to enhance the safety and efficacy of products that treat blood coagulation disorders. The successful candidate will receive mentoring on fulfilling the project, which will also include collaboration with investigators within and external to the FDA.

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

1. Chun H, et al (2022) Blood coagulation factor VIII and LRP1 interact dynamically via switching alternative canonical bivalent and non-canonical electrostatic contacts. J. Thromb. Haemost. 20(10):2255-69.
2. Shestopal SA, et al (2022) Isolated variable domains of an antibody can assemble on blood coagulation factor VIII into functional Fv-like complex. Int. J. Mol. Sci. 23(15):8134.
3. Marakasova ES, et al. (2021) Molecular chaperone RAP interacts with LRP1 in a dynamic bivalent mode and enhances folding of the ligand-binding regions of LDLR family receptors. J. Biol. Chem. 297(1):100842-59.
4. Chun H, et al. (2021). Characterization of protein unable to bind von Willebrand factor in recombinant factor VIII products. J. Thromb. Haemost. 19(4):954-66.
5. Shestopal SA, et al. Expression and characterization of a codon-optimized blood coagulation factor VIII. J Thromb Haemost. 2017;15(4):709-20.
6. Kurasawa JH, et al. Mapping the Binding Region on the Low Density Lipoprotein Receptor for Blood Coagulation Factor VIII. J Biol Chem. 2013;288(30):22033-41.
7. Kurasawa JH, et al. Cluster III of low-density lipoprotein receptor-related protein 1 binds activated blood coagulation factor VIII. Biochemistry. 2015;54(2):481-9.
8. Kurasawa JH, et al. Insect cell-based expression and characterization of a single-chain variable

antibody fragment directed against blood coagulation factor VIII. Protein Expr Purif. 2013;88:201-6.

Anticipated Appointment Start Date: May 1, 2023; 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 four 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 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 must have received or be currently pursuing a Ph.D. or MS in one of the relevant fields. The degree must be received before the start of the appointment and within 5 years of the appointment start date.

Preferred skills/ knowledge:

- Biochemistry and Molecular Biology
  - Designing and cloning plasmid constructs, bacterial and tissue cultural techniques
  - Recombinant protein expression and purification
  - PAGE/Western blot protein analysis and performing respective functional / binding assays
- Chemical Kinetics and Surface Plasmon Resonance Technique

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **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** (48 👁)

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.)

and

Do you expect to receive your degree prior to the start of the appointment?