Opportunity Title: FDA Biochemistry of Blood Coagulation Fellowship
Opportunity Reference Code: FDA-CBER-2020-0016

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

Reference Code FDA-CBER-2020-0016

How to Apply 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 2/5/2021 3:00:00 PM Eastern Time Zone

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

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 research opportunity 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 selected participant will receive mentoring on fulfilling the project, which will also include collaboration with investigators within and external to the FDA. The participant will be studying mechanisms of interactions of blood coagulation factor VIII with its plasma clearance receptors, and learn various methodologies to model and test these interactions in vitro.

The following papers provide examples of the research performed within the group:

1. Shestopal SA, Hao JJ, Karnaukhova E, Liang Y, Ovanesov MV, Lin M, et al. Expression and characterization of a codon-optimized blood coagulation factor VIII. J Thromb Haemost. 2017;15(4):709-20.
2. Kurasawa JH, Shestopal SA, Karnaukhova E, Struble EB, Lee TK, Sarafanov AG. Mapping the Binding Region on the Low Density Lipoprotein Receptor for Blood Coagulation Factor VIII. J Biol Chem. 2013;288(30):22033-41.
3. Kurasawa JH, Shestopal SA, Woodle SA, Ovanesov MV, Lee TK, Sarafanov AG. Cluster III of low-density lipoprotein receptor-related protein 1 binds activated blood coagulation factor VIII. Biochemistry. 2015;54(2):481-9.
4. Kurasawa JH, Shestopal SA, Jha NK, Ovanesov MV, Lee TK, Sarafanov AG. 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, 2020

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

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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 should have received a Master's or Doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Biochemistry and molecular biology, such as 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
- Knowledge of 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 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)