**Opportunity Title:** FDA Fellowship on the Biochemical Mechanisms of Blood Coagulation
**Opportunity Reference Code:** FDA-CBER-2023-37

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

**Reference Code** FDA-CBER-2023-37

**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** 12/29/2023 2:52:44 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. 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. Sarafanov AG (2023). Plasma clearance of coagulation factor VIII and extension of its half-life for the therapy of hemophilia A: a critical review of the current state of research and practice. Int. J. Mol. Sci. 24: 8584.

2. 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.

3. 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.

4. 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.

5. 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.

6. Shestopal SA, et al. Expression and characterization of a codon-optimized blood coagulation

factor VIII. J Thromb Haemost. 2017;15(4):709-20.

7. 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.

8. 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.

9. 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: October 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 7 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 Biological/Life Sciences, Chemistry, 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.

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PREFERRED SPECIALIZED EXPERIENCE: Skill in in 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 is desirable. Knowledge of chemical kinetics and surface plasmon resonance technique is also desirable.

**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** (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.)

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

and

I have read the FDA Ethics Requirements.