**Opportunity Title:** FDA Fellowship - Analysis of Codon Optimized FIX and FVIII Delivered by Adeno Associate Virus
**Opportunity Reference Code:** FDA-CBER-2026-0070

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

**Reference Code** FDA-CBER-2026-0070

**How to Apply** ***To submit your application, scroll to the bottom of this opportunity and click 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** 7/31/2026 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), Food and Drug Administration (FDA) in White Oak, Maryland

The Center for Biologics Evaluation and Research (CBER) is one Center within the Food and Drug Administration, an Agency within the United States Government's Department of Health and Human Services. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

**Research Project:** The successful candidate will join the research project that supports ongoing investigations into the functional and structural consequences of synonymous codon substitutions and codon optimization in the context of therapeutic biologics. You will be a part of studies examining how codon optimization and naturally occurring synonymous variants modulate gene expression, translational kinetics, RNA secondary structure, protein folding, post-translational modifications, and immunogenicity. Model systems include recombinant coagulation factors (Factor VIII, Factor IX, ADAMTS13/MDTCS) expressed across multiple platforms, including transient transfection, lentiviral delivery, AAV-mediated gene delivery, and targeted genomic integration. Techniques may include ribosome profiling, tRNA sequencing, proteomics, glycoproteomics, mass spectrometry, structural characterization assays, and high-throughput cell-based assays.

**Learning Objectives:** Under the guidance of a mentor, you will have the opportunity to:

1. Develop proficiency in molecular biology techniques relevant to recombinant protein expression, including cell culture, transient

transfection, lentiviral and AAV-mediated gene delivery, and stable genomic integration systems.
2. Learn to apply proteomics and glycoproteomics workflows, including mass spectrometry-based post-translational modification analysis, to evaluate protein quality attributes of therapeutic biologics.
3. Develop skills in structural characterization of recombinant proteins using conformation-sensitive antibody panels, circular dichroism, and/or Ankyron-based assays.
4. Gain experience in computational analysis of codon usage metrics (e.g., CAI, codon-pair optimization, RNA secondary structure modeling) and their integration with experimental data.

**Mentor:** The mentor for this opportunity is Chava Kimchi-Sarfaty (chava.kimchi-sarfaty@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

**Anticipated Appointment Start Date: August 1, 2026.** Start date is flexible and will depend on a variety of factors.

**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.

**Participant Stipend:** The participant will receive a monthly stipend commensurate with educational level and experience.

**Citizenship Requirements:** This opportunity is available to U.S. citizens only and Legal Permanent Residents (LPRs).

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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 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

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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 must have received or be currently pursuing a master's or doctoral degree in one of the related fields: pre-med, life/health/medical sciences, biochemistry, chemistry, and/or genetics. The degree must be received within the past five years or be currently pursuing.

**Preferred skills:**

- Basic knowledge of biology or biochemistry
- Familiarity with codon optimization using in vitro methods
- Experience with cell culture, protein purification, Western blots
- Willing to research with antibodies, recombinant proteins and gene therapy

**Point of Contact**

Ashley

**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** (1 👁)
  - **Engineering** (4 👁)
  - **Life Health and Medical Sciences** (8 👁)

**Affirmation**

I am a U.S. citizen, or 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.)
and
I have read the FDA Ethics Requirements.