Opportunity Title: FDA Fellowship - Development and Evaluation of Gene Therapy for Rare Neuromuscular and Neurological Diseases
Opportunity Reference Code: FDA-CBER-2026-0015

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

Reference Code FDA-CBER-2026-0015

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 5/15/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: Two research opportunities are currently available at the Office of Gene Therapy (OGT), Office of Therapeutic Products (OTP), Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA) in Silver Spring, 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 candidates will contribute to projects focused on the development and validation of regulatory-relevant preclinical disease models to support the evaluation of gene therapies for rare neurological and neuromuscular disorders.

Examples of potential projects are listed below; specific assignments will be tailored to each candidate's interests and background:

1. Investigation of prenatal gene therapy interventions, including the development of tools to evaluate fetal–maternal AAV transfer, AAV integration, and biodistribution in preclinical disease models.
2. Development of novel genomic methods to assess neurotoxicity associated with AAV-based gene therapies.

This research will generate critical safety and efficacy data to inform regulatory evaluation of these emerging therapeutic modalities.

Learning Objectives: If selected, you will have the opportunity to:

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1. Develop an understanding of the molecular mechanisms underlying neuromuscular and neurological diseases;
2. Gain expertise in the design and production of AAV vectors for delivering therapeutic genes in preclinical disease models;
3. Learn to perform and analyze functional assays to evaluate therapeutic technologies; and
4. Acquire, synthesize, and effectively communicate research findings.

Mentor: The mentor for this opportunity is Dwi U. Kemaladewi (Dwi.kemaladewi@fda.hhs.gov), Ph.D., Principal Investigator and Senior Staff Fellow at CBER. If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: Mid-May, 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, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 should have received a doctoral degree in one of the relevant fields listed under Eligibility Requirements below. The doctoral degree must be received within the last 60 months or anticipated before start date (thesis approval letter may be requested).

Preferred skills/ knowledge:

- Demonstrated proficiency with models of human diseases, supported by primary authorship in peer-reviewed journal(s).
- Candidates with experience in organoid/assembloid-based modeling for neurological indications are especially invited to apply.
- Experience in drug developments/therapeutic evaluations, including but not limited to genome editing, viral vectors, LNPs
- Experience in analysis of single cell and/or spatial transcriptomics

Point of Contact

Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Engineering** (29 👁)
  - **Life Health and Medical Sciences** (51 👁)
  - **Mathematics and Statistics** (11 👁)
  - **Science & Engineering-related** (1 👁)

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.