Opportunity Title: FDA Postdoctoral Fellowships in Cell and Gene Therapy
Opportunity Reference Code: FDA-CBER-2026-0016

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

Reference Code FDA-CBER-2026-0016

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
- Two educational or professional recommendation
- Applicants may indicate interest in Project Area 1, Project Area 2, or both in their cover letter.

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 5/22/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: Two postdoctoral ORISE Fellowships are available in the laboratory of Dr. Nirjal Bhattarai in the Office of Therapeutic Products (OTP) at the 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 Projects:

Project Area 1: Cell and Gene Therapy Safety
This project focuses on improving the safety of gene therapy products, including AAV vectors, through mechanistic and translational laboratory studies. The fellow will assess quality attributes (CQAs) that may influence safety-related outcomes, such as immunogenicity and inflammatory toxicities. Using various model systems, the fellow will identify process parameters that are safety-relevant and develop strategies to mitigate these risks while preserving overall product performance.

Project Area 2: New Approach Methodologies (NAMs) for Cell and Gene Therapy
This project focuses on developing NAMs for the safety and efficacy assessment of gene

therapy products, including AAV vectors and gene-modified immune cells. The fellow will develop and apply innovative in vitro model systems and analytical platforms, including microfluidic systems and advanced material-based platforms, to better understand product performance, biological responses, and safety-related outcomes. These studies will support identification of CQAs and product- or process-related factors that may influence therapeutic activity, toxicity, or other key outcomes.

Learning Objectives: Under the guidance of a mentor, you will:

- **Develop expertise in cell and gene therapy product assessment:** Gain hands-on experience evaluating the safety, efficacy, and mechanistic behavior of AAV vectors and gene-modified immune cells.
- **Apply advanced experimental approaches:** Learn to use gene modulation methods (for example, siRNA and CRISPR), cytokine profiling, flow cytometry, cytotoxicity assays, co-culture systems, microfluidics, and biomaterial-enabled model platforms.
- **Investigate mechanisms underlying product performance and biological response:** Study immune activation, inflammatory toxicities, immune-cell interactions, and other determinants of therapeutic activity in physiologically relevant systems.
- **Identify determinants of quality and function:** Examine how product attributes and manufacturing-related variables influence CQAs, therapeutic function, immune responses, and safety-related endpoints.
- **Integrate translational science with regulatory considerations:** Build understanding of how mechanistic studies and innovative model systems inform regulatory science, product evaluation, and risk mitigation strategies for next-generation therapies.
- **Strengthen scientific communication and interdisciplinary collaboration skills:** Present findings in internal and external scientific forums, contribute to peer-reviewed publications, and collaborate with multidisciplinary teams across immunology, molecular biology, toxicology, bioengineering, and materials science.

Mentor: The mentor for this opportunity is Nirjal Bhattarai (Nirjal.Bhattarai@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: September 10, 2026 or earlier. 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 and Lawful Permanent Residents (LPR) only.

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 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 should have received a doctoral degree in the one of the relevant fields (bioengineering, biomedical engineering, chemical engineering, materials science, biological sciences, or a related discipline). Degree must have been received within the past five years.

Applicants may indicate interest in Project Area 1, Project Area 2, or both in their cover letter.

Preferred skills:

- Experience aligned with either research area is desirable.
- For the gene therapy project, experience in AAV gene therapy is advantageous.
- For the NAMs project, a strong background in microfluidics and

materials science is preferred; experience in cell and gene therapy, AAV biology, or immune cell engineering is also desirable.
- Strong collaborative skills and excellent written and oral communication skills.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (18 👁)
  - **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.