Opportunity Title: FDA Fellowship - Understanding the Role of the Manufacturing Microenvironment on the Safety and Efficacy of Cellular Therapies
Opportunity Reference Code: FDA-CBER-2026-0008

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

Reference Code FDA-CBER-2026-0008

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 5/22/2026 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 Center for Biologics Evaluation and Research (CBER), in the Office of Therapeutic Products (OTP), under the Office of Cellular Therapy & Human Tissue (OCTHT), 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: CBER's mission is to ensure the safety, purity, potency, and effectiveness of biological products including vaccines, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. The project will utilize a variety of approaches including large scale cell manufacturing, extracellular vesicle manufacturing and characterization, biomaterials, high content imaging, and multiomics. The overall project goals are as follows:

- Assess effect of 'advanced manufacturing microenvironments' on therapeutic cell growth and production of immunomodulatory factors (such as extracellular vesicles).
- Identification of in-process factors produced during the manufacturing process that can predict cell quality.
- Design of scalable, tunable 3D biomaterial environments that enhance cell production of immunomodulatory factors.

Learning Objectives: You will have the opportunity to learn how biomedical engineering

tools would be used in the assessment of regenerative medicine advanced therapeutic products such as cellular and tissue engineered products.

Mentor: The mentor for these opportunities is Ross A. Marklein (ross.marklein@fda.hhs.gov) If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: June 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, 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 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

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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 doctorate in one of the relevant fields (biomedical engineering) or currently pursuing and anticipated to receive by the appointment onboarding. Degree must have been received within the past five years or be currently pursuing.

Preferred skills:

- 5 or more of the following research areas/techniques:
  - cell culture (i.e. cell manufacturing)
  - extracellular vesicle manufacturing and characterization
  - high content imaging
  - biomaterials
  - bioreactors
  - multiomics (proteomics/metabolomics)
  - immunology
  - machine learning/AI
  - single cell profiling

Point of Contact

Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (51 👁)

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.