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Opportunity Title: FDA Internship - Impact of Soluble Versus Adhesive Presentation of Heparan Sulfate on Mesenchymal Stromal Cell Production of Extracellular Vesicles
Opportunity Reference Code: FDA-CBER-2026-0069

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

Reference Code FDA-CBER-2026-0069

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 8/14/2026 1:14:38 PM Eastern Time Zone

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

FDA Office and Location: A post-baccalaureate research opportunity is 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: The Marklein laboratory is seeking a highly motivated postbac intern to join a multidisciplinary research team with the following overall goal: “Development of generalizable strategies to define and understand the role of the manufacturing microenvironment on the safety and efficacy of cellular therapies.” This internship will be specifically focused on developing a high throughput approach to screen the impact of heparin sulfate variants on mesenchymal stromal cell (MSC) production of extracellular vesicles (EVs).

Learning Objectives: As the selected postbac intern, you will receive exceptional training opportunities in cell therapy research, combining expertise in advanced manufacturing platforms (bioreactors/biomaterials), high content imaging, and extracellular vesicle characterization. Specific learning objectives include:

- Gaining hands-on experience with advanced cell culture techniques,

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extracellular vesicle isolation and characterization. This will include characterization of MSC-EVs from different cell-lines and produced in different manufacturing conditions (2D vs. 3D and using different surface-coated layer-by-layer assemblies)
- Gain experience in developing an image-based screening approach to identify heparan sulfate surface coatings and soluble heparin sulfate formulations (as well as potential combinations) that enhance MSC-EV production.
- Professional development through publication in high-impact journals and presentation at national conferences as well as preparation for future careers related to product research and development, quality control, regulatory science, and clinical translation

Mentor: The mentor for this opportunity is Ross Marklein (ross.marklein@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).

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

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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 The qualified candidate should have received or be currently pursuing a bachelor's in one of the relevant fields (biomedical engineering). Degree must have been received within the past five years or be currently pursuing.

- **Preferred experience in the following:**
  - 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

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Engineering** (29 👁)

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.