

Opportunity Title: FDA Fellowship in Investigation of the Effect of Cell-Materials Interaction on Cellular Products

Opportunity Reference Code: FDA-CBER-2023-06

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

Reference Code FDA-CBER-2023-06

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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@oraui.org. Please include the reference code for this opportunity in your email.

Application Deadline 6/30/2023 3:00:00 PM Eastern Time Zone

Description **Applications will be reviewed on a rolling-basis, and this posting will remain open until filled.*

A research opportunity is available in the Division of Cellular and Gene Therapies (DCGT), Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) in Silver Spring, MD.

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 selected participant 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. The project will employ a variety of approaches including Microfluidics, Biomaterials engineering, Cell-materials imaging, and Molecular biology.

Under the guidance and direction of a lead investigator, the applicant will apply engineering and microbiology techniques to investigate novel methods for evaluating the biological activity of cell-based products within the context of cellular product development and clinical applicability. The overall objective is to understand how such technologies could be employed in the assessment of cell-based products.

Anticipated Appointment Start Date: First Half of 2023 (start date is flexible)

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 initial appointment is for one year, but may be renewed upon recommendation of FDA**



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contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. **An allowance for health insurance will be provided.** Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. 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 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 a Ph.D. or be currently pursuing the degree with completion expected prior to the appointment starting date in a related field such as Biomedical Engineering, Chemical Engineering, Cell Biology, or Materials Science. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Experience in microfluidics
- Experience with 3D in vitro system
- Experience in cell and molecular biology
- Possess an understanding of high-throughput screening, immunology, and tissue engineering
- Experience in various imaging technologies and molecular biology technologies

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Engineering** (27 )
 - **Life Health and Medical Sciences** (48 )

Affirmation

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.)

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I will receive my degree prior to the start of the appointment.