

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

Opportunity Reference Code: FDA-CBER-2022-45

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

Reference Code FDA-CBER-2022-45

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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 12/31/2022 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 receive training on how practical microsystems 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, High-resolution 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: Fall, 2022 (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 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,



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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 be currently pursuing or have received a bachelor's or master's degree in one of the relevant fields (Biomedical Engineering, Biology, or other Biological/Physical Sciences), or be currently pursuing one of the degrees with completion by December 16, 2022. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Experience in advanced techniques in immunology
- Experience with flow cytometry is highly desirable
- Familiarity with basic techniques and principles in cell and molecular biology and biochemistry would be desirable
- Willing to learn new technologies and methods and operate outside their comfort zone will be strongly preferred

Eligibility Requirements

- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 months or anticipated to be received by 12/16/2022 11:59:00 PM.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** ([12](#) )
 - **Computer, Information, and Data Sciences** ([1](#) )
 - **Engineering** ([27](#) )
 - **Life Health and Medical Sciences** ([48](#) )

Affirmation Applicants must have physically resided in the United States for three of the past five years, regardless of U.S. citizenship or permanent residency status.