

Opportunity Title: FDA Fellowship in Development of Improved Methods for

Assessing Cell Therapies

Opportunity Reference Code: FDA-CBER-2022-22

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

Reference Code FDA-CBER-2022-22

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Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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.

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

A research opportunity is currently available in the Office of Tissues and Advanced Therapies (OTAT) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

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 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, Cell-materials imaging, and Molecular biology.

Anticipated Appointment Start Date: As soon as a qualified candidate is identified; 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 six months, 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. 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



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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 a doctoral degree in one of the relevant fields (e.g. Biomedical Engineering, Chemical Engineering, Cell Biology, Materials Science).

Preferred skills:

- Experience in mammalian cell culture, extracellular vesicle (EV) manufacturing and characterization, and/or cell and molecular biology
- Understanding of high-throughput screening, immunology, and tissue engineering
- · Experience in imaging technologies and molecular biology technologies

Eligibility

• Degree: Currently pursuing a Doctoral Degree.

Requirements

- Discipline(s):
 - Engineering (27 ●)
 - Life Health and Medical Sciences (48.●)

Affirmation Have you 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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