

Opportunity Title: FDA Postdoctoral Fellow - Stem Cell Differentiation **Opportunity Reference Code:** FDA-CBER-2024-0038

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

Reference Code FDA-CBER-2024-0038

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 <u>Click here for detailed information about acceptable</u> <u>transcripts</u>
- 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 <u>ORISE.FDA.CBER@orau.org</u>. Please include the reference code for this opportunity in your email.

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Application Deadline 3/31/2025 3:00:00 PM Eastern Time Zone

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

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

The ORISE Research Participation Program at the U.S. Food and Drug Administration is an educational and training program designed to provide college students, recent graduates, and university faculty opportunities to connect with the unique resources of the FDA. With the support of an assigned mentor, participants have authentic hands-on research experience and allows them access to unique research opportunities, top scientists and engineers, and state-of the art facilities and equipment. 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 cellular and gene therapies.

Research Project: The Stem Cell Engineering laboratory in FDA/CBER's Office of Gene Therapy is seeking a postdoctoral research fellow to research on hematopoietic differentiation of human induced pluripotent stem cells (iPSCs). The candidate will use cell engineering techniques to derive functional lymphocytes for evaluating safety and efficacy of advanced therapies. In addition, the candidate will use molecular biology techniques to identify markers for investigating heterogeneity of stem cell-

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derived cellular products.

Learning Objectives:

- Gain understanding of molecular mechanisms underlying hematopietic and lymphoid commitment.
- Acquire knowledge in designing functional in vitro and in vivo assays for evaluating therapeutic products.
- Learn to acquire, summarize and report research data for scientific communication.

Anticipated Appointment Start Date: December 9, 2024. 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.

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 <u>Guidelines for Non-U.S. Citizens</u> <u>Details page</u> 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 <u>FDA Ethics for Nonemployee Scientists</u>.

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 doctoral degree in one of the relevant fields (molecular & cell biology, immunology, developmental biology, bioengineering, or any related disciplines). Degree must have been received within the past five years.

This is a training opportunity. Applicants must be US citizens or legal residents who have resided in the US for at least 3 of the previous 5 years and have fewer than five years of postdoctoral experience. No option for H1B visa in this position. Please provide your CV and a cover letter including career goals.

Preferred skills:

- Demonstrated proficiency in biomedical research supported by primary authorship in peer-reviewed journal(s).
- Experience in mammalian cell culture, preferably human stem cells.
- Proficient with standard molecular and cell biology methods including flow cytometry, viral or non-viral gene transfers, molecular cloning, immunoassays, quantitative real-time or digital droplet PCR. Small animal handling experience is a plus.
- Excellent organizational and statistical skills, with creativity, selfmotivation, and the ability to assimilate new information from multiple sources.
- Eligibility Degree: Doctoral Degree received within the last 60 month(s).
- Requirements Discipline(s):
 - Engineering (<u>3</u>
 - 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.