Opportunity Title: FDA Cellular Therapeutics Fellowship
Opportunity Reference Code: FDA-CBER-2024-0023

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

Reference Code FDA-CBER-2024-0023

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App 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.**

FDA Office and Location: A research opportunity is available immediately in the Division of Cell Therapy (DCT2), within the Office of Cellular Therapy and Human Tissue (OCTHT) at the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA) located 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: 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. This appointment's research is focused on understanding the advanced manufacturing of CRISPR/Cas9-edited cellular therapeutics. Using CRISPR/Cas9 genome editing tool, we are developing methods for derivation and expansion of various cell therapy products through cellular reprogramming.

Learning Objectives: Under the guidance of a mentor, the successful candidate will learn about CRISPR/Cas9 genome editing tools, perform laboratory research using CRISPR/Cas9 genome editing tool in human pluripotent stem cells (iPSCs) and hematopoietic stem and progenitor cells, and receive training and use advanced manufacturing tools (such as bioreactors) to better understand the ex vivo expansion and manufacturing of genetically modified cellular therapeutics. Laboratory activities will

involve handling and culture of iPSCs and HSPCs, ex vivo genome modification, expansion of cells in bioreactors, characterization of cells by advanced multi-parameter flow cytometry, next-generation sequencing, and bioinformatics analysis. In addition, participants will gain experience on experimental design and its execution, will learn how to use various softwares for data analysis, and will engage in preparation of scientific manuscripts and presentation.

Anticipated Appointment Start Date: June 1, 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 Guidelines for Non-U.S. Citizens Details page 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 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 be currently pursuing or have received a master's or doctoral degree in the one of the relevant fields (e.g. Biology/Biochemistry/Stem cell/Developmental biology/Biomedical Sciences/Bioengineering). Degree must have been received within the past five years, or is currently pursuing.

Preferred skills/experience:

- Less than three years of postdoctoral experience.
- Prior experience with stem cells and CRISPR/Cas9 genome editing technology is preferred.
- A strong background in molecular and cellular biology, NGS analysis, Flow cytometry, Xenotransplantation model and immunological assays are plus.
- Experience in cell/gene therapy product manufacturing is highly desirable.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Communications and Graphics Design** (6 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (51 👁)

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.)
and
I have read the FDA Ethics Requirements.