

Opportunity Title: FDA Cellular Therapeutics Fellowship

Opportunity Reference Code: FDA-CBER-2022-03

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

Reference Code FDA-CBER-2022-03

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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
- A cover letter including career goals (upload in the writing sample section)
- Three educational or professional recommendations

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.

Description *Applications will be reviewed on a rolling-basis, and this opportunity 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.

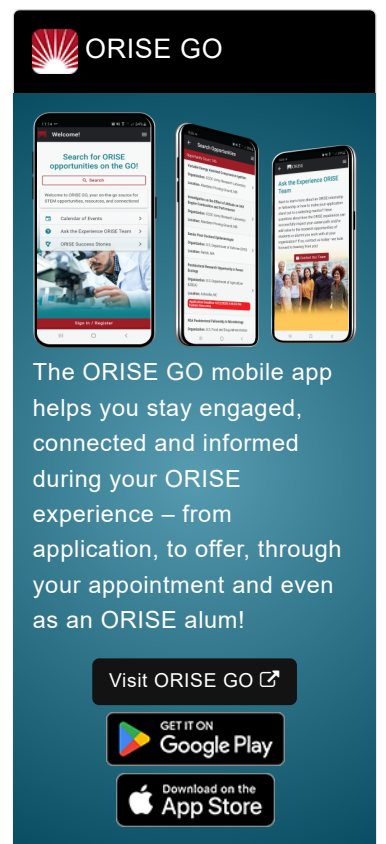
Our research is focused on understanding the advanced manufacturing of CRISPR/Cas9-edited cellular therapeutics. Under the guidance of a mentor, the participants will be trained on CRISPR/Cas9 genome editing in human hematopoietic stem cells and other cell types and will use advanced manufacturing tools to better understand the ex vivo expansion and manufacturing of CRISPR-based cellular therapeutics.

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 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. 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



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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 doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred skills:

- Prior working experience with hematopoietic stem cells and CRISPR/Cas9 genome editing technology
- Strong background in molecular and cellular biology, NGS analysis, Flow cytometry, Xenotransplantation model and immunological assays
- Industrial working experience in cell/gene therapy product manufacturing

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Engineering** ([27](#))
 - **Life Health and Medical Sciences** ([46](#))

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.)