Opportunity Title: FDA Postdoctoral Fellowship in Cellular and Molecular Biology
Opportunity Reference Code: FDA-CBER-2020-0030

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

Reference Code FDA-CBER-2020-0030

How to Apply

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.

Application Deadline 9/14/2020 3:00:00 PM Eastern Time Zone

Description

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

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

The main aim of this project is to examine the critical quality attributes (CQA) of CAR-T cell products manufactured by conventional and automated advanced manufacturing systems including closed/contained and bio-reactor platforms. A large number of CAR-T cells are needed to characterize CQAs in vitro and study safety and bio-distribution of CAR-T cells in vivo in mouse models of human cancers. The project aims at studying important issues of product manufacturing, which should be flexible, scalable and reproducible ensuring GMP-compliant products and finally should be cost-effective.

The research will focus on comparative assessment of CQA of human CAR-T cell product targeted to IL-13Ra2 (phenotypic and functional assessment) produced by different platform technologies. The study will also focus on optimization of critical process parameters for the isolation, activation and transduction of T cells by lentiviral vectors for production of CAR-T cells. The manufacturing technologies may include closed system, conventional approach and bioreactor expansion of CAR-T cells. Under the guidance of a mentor, the participant will learn how to produce, purify and evaluate lentiviral gene therapy vectors and test them in vitro and in vivo animal models of human cancers.

Anticipated Appointment Start Date: as early as May 8, 2020

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

Opportunity Title: FDA Postdoctoral Fellowship in Cellular and Molecular Biology
Opportunity Reference Code: FDA-CBER-2020-0030

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 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, or be currently pursuing the degree and will reach completion by the appointment start date. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Experience in the purification and characterization of proteins in mammalian systems
- Basic recombinant DNA techniques
- Excellent tissue culture techniques
- Experience with molecular, virological and immunological assays including flow-cytometry, measuring T-cell mediated immune responses, ELISpot and ELISA
- Willingness to learn new technologies and methods including animal models of human cancers

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)