Opportunity Title: FDA Postdoctoral Fellowship in Lentiviral Vector Manufacturing
Opportunity Reference Code: FDA-CBER-2020-0037

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

Reference Code FDA-CBER-2020-0037

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 12/31/2020 3:00:00 PM Eastern Time Zone

Description

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

Two research opportunities are currently available with the Division of Cellular and Gene Therapies (DCGT), 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.

An important mission at CBER is to protect and advance public health by ensuring the safety and efficacy of gene-based and cell-based therapeutic products. To support this mission, the work of the DCGT includes projects dealing with manufacturing issues for gene therapy vector products.

Viral vectors, including lentiviral vectors have emerged as important tools for treating genetic and acquired human diseases. As clinical studies have progressed there has been a growing demand for large amounts of purified vectors. A common approach for generating lentiviral vectors involves transient transfection methods involving adherent cells. The vector containing cell culture supernatant is concentrated and purified using chromatography tools. We plan to improve lentiviral vector production by generating stable producer cell lines and by implementing affinity chromatography methods to improve vector purity and to investigate suspension cells for vector manufacturing. We expect that the studies proposed will have an impact on developing improved lentiviral vector manufacturing approaches.

A major drawback for the use of lentiviral vectors in clinical applications is that the large-scale manufacturing and downstream processing methods for these vectors is challenging. Our investigations aim at developing simplified and scalable manufacturing and purification approaches for lentiviral vectors. Our research allows us to evaluate the technologies used to manufacture and test lentiviral vectors (purity) and to determine how changes in the manufacturing process affect their potency and safety. The information gained from these studies will enable us to identify potential risks associated with manufacturing and evaluating lentiviral vectors for clinical use.

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Our approach offers potential advantages of enhanced therapeutic effects and safety, and reduced side effects. The knowledge we gain from the studies proposed will have a general impact on developing safer lentiviral vectors for gene therapy. It will also inform FDA scientists and reviewers involved in policy and guidance development and in evaluating the safety and efficacy of lentiviral vectors.

The goal of this research opportunity is to involve the selected participants, under the guidance of a mentor, in laboratory research that is important both to CBER and the field of gene therapy. The research proposed will allow the participants to gain independence in designing and carrying out laboratory experiments and generating data for publications and presentation. An additional goal is to prepare the participants for the next step in their careers.

Anticipated Appointment Start Date: September 23, 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 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 with molecular and cellular biology techniques

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- Experience with protein purification
- Ability to keep up with pertinent literature and incorporate appropriate concepts and techniques into research activities and experiments
- Ability to collect, record, organize, and analyze experimental data
- Ability to maintain thorough and complete records of experiments, standard operating procedures, and data

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 9/23/2020 11:59:00 PM.
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Science & Engineering-related** (1 👁)