Opportunity Title: FDA Fellowship in the Evaluation of the Safety and Efficacy of Live Attenuated Leishmania Parasite Vaccines
Opportunity Reference Code: FDA-CBER-2024-0021

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

Reference Code FDA-CBER-2024-0021

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.

Application Deadline 8/31/2024 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 in the Office of Blood Research and Review (OBRR) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

Research Project: The FDA laboratory has been conducting collaborative research on the evaluation of safety and efficacy characteristics of live attenuated Leishmania parasite strains (LmCen-/- and LmexCen-/-) using several pre-clinical models and multi-omic approaches. The proposed research involves the application of state of the art methods such as single cell RNA-Seq/ATAC seq/spatial transcriptomics on preclinical animal models towards understanding the mechanisms of pathogenesis and defining correlates of protection. The fellow will be involved in our ongoing research studies focused on assessing the safety and immunogenicity of live attenuated centrin deleted Leishmania major parasites (LmCen-/-) using transcriptomic and metabolomic approaches.

Learning Objectives: The opportunity to research on this project will allow the research fellow to acquire experience in methodologies involved in evaluating safety and immunogenicity of genetically attenuated LmCen-/- parasites. Further training in our laboratory at the FDA will advance the research fellow's education to become a successful applied researcher in an area that is of high medical relevance. In addition, this research fellowship will learn how CBER fulfills its mission of improving global public health.

Anticipated Appointment Start Date: June 3, 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 and Lawful Permanent

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Residents (LPR) only.

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 have received a doctoral degree in one of the relevant fields or currently pursuing with an expected graduation date of May 31, 2024. Degree must have been received within the past five years.

Preferred skills:

- Ph.D. with a focus on molecular biology and vaccinology preferred;
- Excellent communication skills and proficiency in basic bioinformatics skills.
- Strong drive for lab research and some background in vaccinology and Immunology.
- Techniques to include, but are not limited to cell culture, ELISA, RT-qPCR, flow-cytometry, sequencing and analytical biochemistry techniques.
- Training will be provided in all techniques but individuals with laboratory experience in molecular biology, and immunology are encouraged to apply.

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 5/31/2024 11:59:00 PM.

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- **Discipline(s):**
  - **Life Health and Medical Sciences** (6 👁)

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.)

I have read the FDA Ethics Requirements.