

Opportunity Title: FDA Fellowship in Evaluating the Safety and Efficacy of Live Attenuated Leishmania Parasites **Opportunity Reference Code:** FDA-CBER-2023-01

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

Reference Code FDA-CBER-2023-01

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A complete application consists of:

- An application
- Transcripts <u>Click here for detailed information about acceptable transcripts</u>
- 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 <u>ORISE.FDA.CBER@orau.org</u>. Please include the reference code for this opportunity in your email.

Application Deadline 5/31/2023 3:00:00 PM Eastern Time Zone

Description A research opportunity is currently available in the Office of Blood Research and Reviews (OBRR) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in collaboration with Ohio State University

This project will evaluate the safety and efficacy characteristics of live attenuated Leishmania parasite strains (LmCen-/- and LmexCen-/-) using several knock out mouse models, multi-omic approaches. The proposed work 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.

Through experience gained from this appointment, the fellow will learn the methodologies involved in evaluating safety and immunogenicity of genetically attenuated LmCen-/- parasites.

Anticipated Appointment Start Date: 1st Quarter 2023; 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 have received a doctoral degree in one of the relevant fields (e.g. Molecular Biology, Virology). Degree must have been received within the past five years.

Preferred Skills:

- Strong drive for lab work.
- Basic Bioinformatics Skills
- Prior laboratory experience with molecular biology, vaccinology, and immunology
- Prior experience with polymerase chain reaction is desirable

• Degree: Doctoral Degree received within the last 60 month(s).

Eligibility

- Requirements Discipline(s):
 - Life Health and Medical Sciences (6)
 - 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.)