Opportunity Title: FDA Post-Bac/Post-Masters Fellow in Microbial Pathogenesis
Opportunity Reference Code: FDA-CBER-2024-02

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

Reference Code FDA-CBER-2024-02

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 12/31/2024 11:59:00 PM Eastern Time Zone

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 Vaccine Research and Review (OVRR) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

Pathogenesis of Clostridiodies difficile Clostridiodies difficile (C. diff) is the leading cause of hospital acquired infectious diarrhea. This project focuses on examining mechanisms of pathogenesis to identify putative targets for the development of novel therapeutics against C. difficile infection. Preliminary research has identified several targets of interest relating to iron acquisition, polyamine biosynthesis/import, and oxygen sensitivity. The first area of interest involves identification of mechanisms of iron acquisition that are used by C. difficile during mammalian infection. Although mammals have developed mechanisms to tightly control the availability of iron, it is a vital nutrient for nearly all bacterial species. As such, bacterial pathogens have evolved specialized mechanisms of acquiring iron from the host, including ferrous iron transporters, heme binding, and siderophores. The second area of interest involved polyamine biosynthesis and import in the pathogenesis of C. difficile. Preliminary data from our lab indicates that polyamines may play a role in signaling sporulation, making the ability to make or acquire these molecules vital for the overall pathogenesis of this organism. The third area of interest involves oxygen sensitivity. Although C. difficile is generally considered a strict anaerobe, it likely encounters low levels of oxygen in the host during normal infection. In the laboratory setting, C. difficile is capable of growth in broth when exposed to an environment containing 2% oxygen. Transcriptional profiling has been performed for each of these conditions and multiple targets have been identified. The post-bac fellow will help in the research of understanding the role of the genes mentioned above and their potential to be the targets of novel therapeutics.

Initial research on this project will focus on creating clean deletion mutants in genes of interest identified from the gene expression data or otherwise identified targets. Once mutants have been made, the fellow will proceed to performing experiments to assess the impact of deletion of these

genes on various phenotypes and eventually on overall virulence in a mouse model of C. difficile infection.

Anticipated Appointment Start Date: July 1st, 2024

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 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 be currently pursuing or have received a bachelor's or master's degree in the one of the relevant fields (e.g. biology, microbiology). Degree must have been received within the past five years.

Preferred skills:

- An interest in microbiology, bacteriology, or infectious disease takes priority
- Basic understanding of molecular biology/microbiological laboratory techniques

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**

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- **Chemistry and Materials Sciences** (5 👁)
- **Environmental and Marine Sciences** (14 👁)
- **Life Health and Medical Sciences** (51 👁)

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.