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Opportunity Title: FDA Fellowship in Molecular Biological Reagents for Characterization of Live Biotherapeutic Products
Opportunity Reference Code: FDA-CBER-2022-37

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

Reference Code FDA-CBER-2022-37

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 12/31/2022 3:00:00 PM Eastern Time Zone

Description ***Application will be reviewed on a rolling-basis**.

A research opportunity is available with the Office of Vaccines Research and Review (OVRR) at the Center for Biologics Evaluation and Research (CBER), U.S. Food & Drug Administration (FDA) in Silver Spring, Maryland.

Live Biotherapeutic Products are preparations of live bacteria that are being investigated for the treatment or prevention of specific human diseases. They include products commonly referred to as probiotics. For use in clinical trials, particularly in more vulnerable subjects, demonstrating the absence of contaminating organisms, especially pathogens, is a major indicator of safety. This can be problematic due to the large number of product organisms, which may obscure typical culture methods. We are attempting to develop specific reagents to eliminate the product organisms to allow detection of contaminants by simple, yet sensitive, culture methods. Among the approaches we are investigating are lysin proteins - derived from bacteriophage, and bacteriocins - proteins that bacteria produce to kill other bacteria. In addition we are developing reagents to specifically label bacteria. These will be used in assays that, in a mixture of therapeutic bacteria, will identify each bacterial species in order to demonstrate potency (number of each viable strain) and stability (potency over time). Modalities being investigated for this aspect of the project include binding domains of lysin proteins, camelid antibodies raised against whole bacteria, and other antibodies against surface structures. Among the laboratory skills that trainees may expect to learn and become proficient at are microbiological technique, DNA cloning, western blot analysis, protein purification, fluorescence microscopy, and flow-cytometry.

Anticipated Appointment Start Date: July 1, 2022. Start date is flexible and will depend on a variety of factors.

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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. **The current stipend rates for this opportunity are $52,000/yr. (Post-Bachelor's), and $58,000/yr. (Post-Master's) plus an additional allowance for health insurance.** 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 bachelor's or master's degree in one of the relevant fields (e.g. Biological Sciences), or be currently pursuing the degree with completion by the appointment start date. Degree must have been received within the past five years.

Preferred Sills/Experience:

- Basic microbiological techniques - preparation of growth media and propagation of bacterial strains
- Basic DNA cloning techniques - preparation of plasmid DNA, PCR, restriction and ligation, and transformation
- Basic electrophoresis techniques - agarose gels for DNA and acrylamide gels for proteins
- Lab experience
- An interest in Microbiology
- It is expected that candidates will be pursuing higher education in graduate school or medical school following this traineeship

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):**
  - **Life Health and Medical Sciences** (48 👁)

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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.)