Opportunity Title: FDA Microbiology Methods Validation Fellowship
Opportunity Reference Code: FDA-CFSAN-2021-0001

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

Reference Code FDA-CFSAN-2021-0001

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.CFSAN@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 12/16/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available at the U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Safety (OFS), Division of Food Processing Science and Technology (DFPST) located in Bedford Park, Illinois.

Proficiency testing and inter-laboratory studies have a major role in developing and implementing guidelines for Model Laboratory Standards and Accreditation requirements of Food Safety modernization Act (FSMA). FSMA necessitates standardization and validation of microbiological methods. Due to rapidly changing technologies and the vast resources required to validate methods, there is a wide gap in the need for bringing new, reliable methods to the field and the availability of independently (and FDA) validated protocols. Validation of both microbiological and chemical analytical methods used by the FDA is one of the most important expected research outcomes. Validation of analytical methods developed by FDA researchers or BAM procedures is critical to ensure that performance characteristics of the analytical methods are known and established. Use of officially validated methods ensures accurate and precise laboratory data that will be universally accepted. FDA does have a systematic approach for conducting method validations effectively. Methods must be validated by subjecting them to conditions of actual use in the field in order to measure their fitness of purpose. Food microbiological method validations present unique challenges because of the problems associated with preparation and distribution of the test samples with known, homogeneous and stable microflora. The Moffett Proficiency Testing program consisting of multidisciplinary team of scientists from both FDA and Institute of Food Safety and Health. The team is involved in detecting and quantifying a variety of pathogens/contaminants in foods; validating analytical methods according to latest ISO 16140 series of Standards and FDA, AOAC guidelines. Studies include development of newer protocols for developing homogenous and stable bulk food samples including dry ingredients (nuts, spices, flours and infant formula), fresh produce, dairy products, seafood, and other manufactured foods.

Under the guidance of a mentor, the participant will be trained in food microbiology and will learn by assisting in laboratory research projects involving bacterial foodborne pathogens. The project

will provide diverse experience and training in the areas of food microbiology, including complex assays such as conventional and rapid assays for detection, identification and enumeration of pathogens in food. The participant will be involved in the following specific tasks, which are not limited to:

1. Studying modern laboratory methods, procedures, data analysis techniques and quality assurance principles.
2. Developing and implementing laboratory and logistical systems for organizing inter-laboratory method validation based on ISO, FDA and AOAC Standards and guidelines.
3. Developing expertise in techniques to screen a range of food matrices using cultural, biochemical, serological and rapid assays such as immune-assays, PCR and sequencing techniques.
4. Preparing and distributing uniform, homogeneous and stable food samples of variety of matrices and precisely manipulated back ground and different target pathogens ranges according to the study designs.
5. Collecting, analyzing, and summarizing inter-laboratory data with detailed method parameters - analyze the proficiency test and method validation data according to ISO 17043, ISO 13528 and ISO 5725 Standards.

Anticipated Appointment Start Date: January 2021

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 two to four months, 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 Bedford Park, Illinois, 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, master's, or doctoral degree in one of the relevant fields, or be currently pursuing the degree with completion by the appointment start date. Degree must have been received within five years of the appointment start date.

Preferred skills:

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- Advanced level of experience in the areas of food microbiology
- Skills in interpretation and evaluation of analytical results to determine validity and scientific significance
- Ability to generate summary reports and manuscript(s), including technical standard operating procedures
- Excellent verbal and written communication skills
- Knowledge and experience with laboratory techniques to screen a range of food matrices, including biochemical, serological, rapid detection assays, immuno-assays, Real-Time PCR and other microbial detection and enumeration techniques
- Experience and research skills such as statistical evaluation and interpretation of laboratory data in validating food analytical methods according to ISO 16140, AOAC and FDA guidelines

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or anticipated to be received by 1/31/2021 11:59:00 PM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (3 👁)