Opportunity Title: FDA Antibacterial Drug Resistance Fellowship
Opportunity Reference Code: FDA-CDER-2020-0504

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

Reference Code FDA-CDER-2020-0504

How to Apply 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. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 9/30/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Office of New Drugs/Office of Antimicrobial Products, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

Antibacterial drug resistance is a major threat to public health. In March 2015, The National Action Plan for Combating Antibiotic-resistant Bacteria was developed in response to Executive Order 13676: Combating Antibiotic-Resistant Bacteria (CARB), which was issued on September 18, 2014. The National Action Plan outlines steps for implementing the National Strategy for Combating Antibiotic-Resistant Bacteria to address urgent and serious drug-resistant threats that affect people in the U.S. and around the world. Implementation of the National Action Plan will also support World Health Assembly resolution 67.25 (Antimicrobial Resistance), which urges countries to take urgent action at the national, regional, and local levels to combat resistance.

FDA's roles in combatting antibacterial drug resistance are to: (1) facilitate the development of new antibacterial drugs to treat patients and (2) advance the science of clinical trial design.

As part of ongoing efforts to harmonize and facilitate the global development of antibacterial drugs, a research project will examine the microbial etiologies of bacterial infections such as hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, community-acquired bacterial pneumonia, complicated urinary tract infections, and complicated intra-abdominal infections in different geographic regions. The epidemiology of resistance phenotypes in different geographic regions will also be evaluated as part of this project.

Under the guidance of a mentor, the selected participant will perform research analysis to analyze pharmacokinetic information obtained from animal models of infection research studies. In addition, the participant will be involved in the following activities: (1) an assessment of renal function variations in patients enrolled in phase 3 studies for complicated urinary tract infections, (2) optimization of the use of nonclinical data to support anti-infective development programs, and (3) an evaluation of different liver staging models and its impact on the pharmacokinetic interpretations of drugs administered to patients.

This program, administered by ORAU through its contract with the U.S. Department of Energy to

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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 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 be in at least the third year of pursuing a doctoral degree. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Ability to think critically
- Strong analytical skills to evaluate complex information relating to the safety and efficacy of drugs, e.g. understanding the mechanism of action of drugs and antimicrobial activity and clinical outcomes
- Excellent written and oral communication skills to effectively communicate complex research findings and recommendations
- Familiarity in the following is strongly preferred:
  - understand pharmacokinetic (PK), pharmacodynamic (PD), and PK-PD analysis principles
  - participated in research that included PK-PD or PK modeling analysis and has hands-on experience, preferably in the anti-infective field
  - training or experience with data analysis tools (e.g., R, MATLAB, or SAS) and modeling tools (e.g., Phoenix NLME, Monolix, or NONMEM)

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)

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Affirmation I have received a doctoral degree within the past 5 years, or am currently in at least the third year of pursuing a doctoral degree.