Opportunity Title: FDA-CDER Antimicrobial PK-PD Fellowship
Opportunity Reference Code: FDA-CDER-2024-1367

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

Reference Code FDA-CDER-2024-1367

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

Application Deadline 3/29/2024 3:00:00 PM Eastern Time Zone

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

CDER Office/Lab and Location: A research opportunity is available in the Office of Infectious Diseases (OID), Office of New Drugs (OND) within the Food and Drug Administration (FDA) located in Silver Spring, Maryland. The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than just medicines.

Research Project: The project seeks to address multiple challenges with current antimicrobial minimum inhibitory concentration (MIC) based pharmacokinetic-pharmacodynamic (PK-PD) methodologies for clinical decision making. Specifically, identification of the true PK-PD target and consideration of its variability by evaluating different bacterial burden and incorporating unconsidered factors (e.g. PD variability). The results of the project are expected to support the implementation of new approaches that ensure high-confidence decision making from a translational pharmacology-regulatory perspective.

Under the guidance of the mentor, the participant will gain a comprehensive understanding of the following components of the antimicrobial development process from a clinical pharmacology regulatory perspective and will be able to translate pharmacological principles into clinical decision-making. The participant's training will include:

- Learning to prepare a database describing antimicrobial PK-PD information gathered from submitted marketing applications and publicly available sources including published literature.
- Learning to evaluate nonclinical infection PK-PD models and apply the

information to translation and selection of the dosing regimen(s) used to support a marketing application as well as set antibacterial susceptibility test interpretive criteria.
- Learning to conduct MIC-based PK-PD analyses (e.g., population pharmacokinetics, Monte Carlo simulations)

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 appointment is for 12 months. 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 have received a master's level degree in Pharmaceutical Science/Pharmacology or received a doctoral degree (e.g. PhD, PharmD, DrPH, MD, etc.) in one of the relevant fields. Familiarity with pharmacokinetics and pharmacodynamics is desired. Degree must have been

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received within five years of the appointment start date.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Life Health and Medical Sciences** (51 👁)
  - **Mathematics and Statistics** (11 👁)

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.)

and

I have read the FDA Ethics Requirements.