**Opportunity Title:** FDA Antimicrobial Pharmacology and Toxicology Fellowship
**Opportunity Reference Code:** FDA-CDER-2024-1385

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

**Reference Code** FDA-CDER-2024-1385

**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** 8/30/2024 3:00:00 PM Eastern Time Zone

**Description**

***Applications will be reviewed on a rolling basis**

The project is located in the Office of Infectious Diseases (OID), Office of New Drugs (OND). This project will use multiple approaches to evaluate existing nonclinical safety data of monoclonal antibodies directed against microbial targets and use this information to further enhance (or improve upon) the current toxicology approach to predict safety for clinical decision-making. Specifically, the outcome of the project may result in a new regulatory approach that: (1) ensures confidence in decision making from a toxicology-regulatory perspective; (2) generates evidence to support and harmonize scientific advice to stakeholders; (3) promote harmonization in CDER divisions on nonclinical review of biologics directed against microbial targets; and (4) further emphasize the need to evaluate new approach methodologies (NAMs).

Under the guidance of the mentor, the participant will gain a comprehensive understanding of the following components of the antimicrobial development process from a pharmacology/toxicology regulatory perspective:

- Nonclinical safety from in vitro and in vivo toxicity studies conducted with monoclonal antibodies; will be able to translate pharmacological/toxicological principles into clinical decision-making.
- Enhanced awareness of the roles and impact of inter-disciplinary groups on antibacterial drug development and FDA commitment to 3'Rs to replace, reduce, and refine use

of animals in research and testing.
- Improved understanding of NAMs and their potential utility in the regulatory landscape of new drug review

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 the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

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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. 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

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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 or doctoral degree in Toxicology or Pharmacology. Degree must have been received within five (5) years of the desired starting date. Familiarity and/or training in the principles of toxicology and/or pharmacology to determine the safety of a chemical, biologic, or drug is desired.

**Preferred Skills and/or Experience:**

- Understanding how chemicals are assessed for safety in vitro and in vivo, and knowing how this data might be used to predict human safety.
- Publication history in peer reviewed journals, scientific abstract/poster
- Hands on training, research, or experience in evaluation of nonclinical safety data for chemicals, drugs, and/or biologic products
- Hands on training, research, or experience with NAMs to determine safety of chemicals, drugs, and/or biologic products.
- Knowledge of ICH and FDA guidance and familiarity with drug development

**Eligibility Requirements**

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (2 👁)

**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.