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Opportunity Title: FDA Immunogenicity Risk Assessment Fellowship
Opportunity Reference Code: FDA-CDER-2024-1456

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

Reference Code FDA-CDER-2024-1456

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click 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

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.

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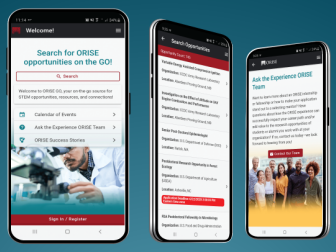

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Application Deadline 12/13/2024 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Quality Research (OPQR), Office of Pharmaceutical Quality (OPQ), located at 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 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.

Research Project: Inflammation can increase the risk of anaphylactic or hypersensitivity reactions, cytokine release syndromes, loss of efficacy and, in rare cases, the onset of long-lasting autoimmune or deficiency syndromes. The effect can be direct, by eliciting an inflammatory or innate immune activation response, or indirect, by inducing anti-drug antibodies. Product and process impurities can enhance the risks by triggering innate immune receptors that foster the accumulation and activation of antigen-presenting cells at the product administration site, improving the processing and presentation of antigen to T cells, and/or directly enhancing the generation of antigen specific antibodies by B cells. They can also activate mast cells and basophils that foster allergic and anaphylactic responses.

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The project will focus on generating in silico, in vitro and in vivo strategies to assess product immunogenicity risk of proteins, oligonucleotides and peptides.

Learning Objectives: The research participants will receive training in the study of development and characterization of in vitro and in vivo model of immune function to assess generic and biosimilar drug products. They will become proficient in in vitro and in vivo modeling and learn about the advantages and limitations of the different models. Throughout the appointment, the fellow will learn about the impact of formulation of bioassays and develop a process to optimize assays to detect impurities. Lastly, the fellow will learn about assay validation.

Anticipated Appointment Start Date: 2024/2025. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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.

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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 or doctoral degree in the one of the relevant fields (e.g. Immunology, Pharmacology, or Immunopathology).

Preferred skills:

- A strong background in innate immunity demonstrated by publications in the field of innate immune response.
- Demonstrated experience in immunology and capable of planning and running complex research experiments and capable of analyzing and interpreting data.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

Affirmation

I am a U.S. citizen, or 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.