

Opportunity Title: FDA Immunogenicity Risk Assessment Fellowship

Opportunity Reference Code: FDA-CDER-2023-1278

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

Reference Code FDA-CDER-2023-1278

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

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

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

Application Deadline 9/30/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available within the Office of Pharmaceutical Quality (OPQ)/ Office of Biotechnology Products (OBP) at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in Silver Spring, Maryland. 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

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

Under the guidance of the mentor, the participant will learn about the innate immune response modifiers. The participant will become proficient in in vitro and in vivo modeling and learn about the advantages and limitations of the different models. The participant will be encouraged to use state of the art technologies to analyze complex data and to engage in critical mechanistic thinking that will enable them to become mature scientists.

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-



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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 There are multiple positions open and candidates with bachelors, master's or doctoral degrees in Immunology, Pharmacology, or Immunopathology will be considered.

Knowledge in the use of animal models and design of experiments is preferred.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Computer, Information, and Data Sciences** ([1](#) )
 - **Life Health and Medical Sciences** ([4](#) )

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.