Opportunity Title: FDA Fellowship in Pharmaco-Immunology
Opportunity Reference Code: FDA-CDER-2023-1268

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

Reference Code FDA-CDER-2023-1268

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 6/30/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in the Office of Pharmaceutical Quality (OPQ)/Office of Biotechnology Products in Silver Spring, Maryland.

This program in the Laboratory of Immunology (OBP) is targeted at dissecting immune-mediated mechanisms underlying the development of tolerance and adverse reactions to therapeutic drugs and immunotherapies, as part of the safety surveillance of drug development. Our lab comprises a multidisciplinary group of scientists with immunology, molecular biology and chemistry expertise that study innate and adaptive adverse immune responses to therapeutics as well as unwanted interactions of drugs with human leukocyte antigen (HLA) risk alleles using patient samples, animal models of drug hypersensitivity reactions, and cutting-edge genomic and proteomic techniques.

Under the guidance of a mentor, the participant's training will include:

- Immunochemistry of Drug-HLA interactions using analytical and biochemical/proteomic methods.
- In vitro evaluation of T cell recognition of therapeutic protein or drug-modified epitopes presented by HLA molecules using cell lines and primary cells.
- Development of in vitro skin and liver-based culture systems to validate immune mediated tissue damage.
- Analysis of HLA transgenic mice as in vivo models for drug and immunotherapy adverse reactions to define experimental conditions of tolerance and disease.

Learning objectives include: a comprehensive understanding of the structural and immunological mechanisms involved in severe adverse drug reactions, learning methods and immunological theory relevant to autoimmunity, immune tolerance and therapeutic protein immunogenicity.

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

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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 bachelor's, master's or doctoral degree in one of the relevant fields, or be currently pursuing a master's or doctoral degree. Degree must have been received within five years of the appointment start date.

Familiarity with molecular and cellular immunology and bioinformatics 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):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (48 👁)

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 received a bachelor's, master's or doctoral degree or am currently pursuing a master's or doctoral degree.