Opportunity Title: FDA Fellowship in Pharmaco-Immunology
Opportunity Reference Code: FDA-CDER-2026-0096

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

Reference Code FDA-CDER-2026-0096

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 6/12/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: 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.

The Center for Drug Evaluation and Research 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, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. These efforts cover more than just medicines.

Research Project: This project in the Laboratory of Immunology focuses on **elucidating molecular and immunological mechanisms underlying immunogenicity and tolerance of therapeutic products.** Products will include FDA approved drugs and proteins, biosimilar proteins, generic peptides, and nanoparticle therapeutics. Project will apply **predictive analytical tools** to identify patient populations at risk for adverse immune responses.

While most patients tolerate therapeutic products without issue, a subset develops **immune-mediated adverse reactions**, often driven by interactions between drug-derived or altered epitopes and the host immune system. These responses are frequently **HLA-restricted** and mediated by **T cell receptor (TCR) recognition**.

Learning Objectives: Under the guidance of FDA scientists, you will gain interdisciplinary training in **immunology, proteomics, molecular biology and translational regulatory science**, including:

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- Understanding **HLA-associated antigen processing and presentation** in the context of therapeutic products
- Gaining hands-on experience with **mass spectrometry-based immunopeptidomics** to identify drug-modified and contaminant-derived epitopes
- Developing skills in **T cell immunology**, including antigen-specific T cell isolation, expansion, functional characterization, and cloning
- Learning **T cell receptor (TCR) sequencing and recombinant expression** for mechanistic and structural studies
- Applying **HLA tetramer technologies** to interrogate antigen-specific immune responses
- Utilizing **HLA transgenic animal models** to study immunogenicity and tolerance in vivo
- Interpreting data in the context of **drug development, product quality, and regulatory evaluation**

Through this training, you will contribute to advancing **predictive frameworks for immunogenicity risk**, with potential applications in **personalized medicine**, including HLA- and TCR-based patient screening strategies.

Mentor: The mentors for this opportunity are Michael Norcross (Michael.Norcross@fda.hhs.gov) and Sujin Hwang (Sujin.Hwang@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: 2026. 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.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

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.

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.

Preferred skills:

- Familiarity with molecular and cellular immunology and bioinformatics

Point of Contact

Ashley

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 👁)

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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.