Opportunity Title: FDA Drug and Vaccine Safety Fellowship
Opportunity Reference Code: FDA-CDER-2022-0818

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2022-0818

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

11/30/2022 3:00:00 PM Eastern Time Zone

Description

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

A research opportunity is available in the Office of Pharmaceutical Quality/ Office of Biotechnology Products (OBP) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), 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.

The ability of lipid nanoparticles (LNP) to encapsulate genetic materials and other APIs for controlled delivery has shown great potential in therapeutics to treat a wide variety of diseases. In 2018, CDER approved the first LNP-based siRNA, patisiran (NDA 210922), for the treatment of hereditary transthyretin-mediated amyloidosis. In 2021, the LNP has been the focus of attention due to the success of mRNA/LNP COVID vaccines. However, there were severe allergic reactions upon first dose of mRNA vaccination that were more frequent than seen with flu vaccine. There are also poorly understood allergic reactions to previously approved LNP-based therapeutics (e.g., patisiran associated infusion reactions), suggesting LNP immunogenicity and perhaps pre-existing immunogenicity to the LNP platforms. So far there are no methods available to detect LNP immunogenicity other than antibody assays to PEG, an ingredient of LNP. If the LNP platform is immunogenic, COVID19 vaccination with mRNA/LNP vaccines might alter the immunogenicity profile in a large population. In this project, we will research a method to detect immunogenicity to the LNP platform, screen sera samples collected before pandemic and post mRNA/LNP vaccination.

Under the guidance of the mentor, the participant will learn state of art technology to detect immunogenicity, flow cytometry and gain large sample handling skills.

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 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 or master's degree in one of the relevant fields, or be currently pursuing one of the degrees with completion by November 30, 2022. Degree must have been received within the past five years.

Eligibility Requirements

- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 months or anticipated to be received by 11/30/2022 11:59:00 PM.
- **Discipline(s):**
  - **Engineering** (1 👁)
  - **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)