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Opportunity Title: FDA CDRH Summer 2021 Research Participation Program
Opportunity Reference Code: FDA-CDRH-2021-Summer

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

Reference Code FDA-CDRH-2021-Summer

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. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

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

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

Application Deadline 7/30/2021 3:00:00 PM Eastern Time Zone

Description ***Although the application deadline is July 30th, mentors will start reviewing submitted applications before the deadline.**

Summer research opportunities are available at the U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) located in Silver Spring, Maryland.

The Oak Ridge Institute for Science and Education (ORISE) Research Participation Program at the U.S. Food and Drug Administration are educational and training programs designed to provide students and recent graduates, opportunities to participate in project-specific research and developmental activities at the Center for Devices and Radiological Health (CDRH).

The mission of CDRH is to protect and promote the public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Participants will have an opportunity to gain a hands-on research experience on a variety of regulatory research projects related to CDRH's mission. The program is designed for participants to engage with an expert mentor or mentors during the summer to examine a question of interest related to those projects within the placement office. Past projects have been related to: evaluation of acoustic noise levels in neonate, tools for regulating 21st-century microbubble products for pharmaceutical delivery, biological sex differences in the safety of vagus nerve stimulation, bioprinting materials performance assessment, microelectrode array recordings from induces pluripotent stem cell-derived neurons, machine learning in image reconstruction, and optical performance characterization of mixed reality devices.

Both full-time and part-time appointments are typically available. Anticipated start day is on or

around May 17, 2021, but can be negotiated with the mentor to commence on any Monday throughout the summer in order to best align with school schedules.

To avoid conflict of interest, participants cannot be placed in the same CDRH program office where a relative works.

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 2-3 months. 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 part-time or 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

These opportunities are open to currently enrolled university students (all levels) at least 18 years of age and recent graduates who have graduated within the past 60 months of the start date. Demonstrated excellence in science-related courses is preferred.

Eligibility Requirements

- **Degree:** Associate's 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 👁)
  - **Computer, Information, and Data Sciences** (15 👁)
  - **Engineering** (12 👁)
  - **Life Health and Medical Sciences** (11 👁)
  - **Mathematics and Statistics** (10 👁)
  - **Physics** (16 👁)
  - **Science & Engineering-related** (1 👁)
- **Age:** Must be 18 years of age