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Opportunity Title: FDA Development of Regulatory Science Tools to Streamline Biocompatibility and Toxicology Evaluations of Medical Devices
Opportunity Reference Code: FDA-CDRH-2024-0019

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

Reference Code FDA-CDRH-2024-0019

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click 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.CDRH@orau.org. Please include the reference code for this opportunity in your email.

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!

Application Deadline 12/31/2024 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available within the Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Laboratories (OSEL), Food and Drug Administration (FDA), located at Silver Spring, Maryland, **or may be remote.**

Research Project: Under the guidance of a mentor, the participant may be involved in the following learning activities:

- Participate in regulatory science research to help develop new approaches without the use of animals to evaluate biocompatibility and toxicology to accelerate patient access to innovative, safe and effective medical devices.
- Collect, analyze, and interpret research data and information from multiple data sources using scientific methods.
- Present data and findings using different platforms (e.g., PowerPoint, Visio, etc.).
- Participate and collaborate with cross-functional teams and experts both internal and external to FDA.
- Stay updated with relevant research trends and/or methodologies to incorporate appropriately in projects.
- Draft and/or publish research findings as regulatory science tools, in scientific journals, and/or in reports.
- Develop and maintain research protocols and documentation

throughout the project.

Learning Objectives: The selected candidate will gain experience in biocompatibility and toxicology in a real-world setting, as well as an understanding of regulatory science, risk assessment, and medical device review processes.

Anticipated Appointment Start Date: 2024. 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.

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;

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- 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 be currently pursuing or have received a bachelor's, master's, or doctoral degree in the one of the relevant fields (toxicology, life sciences, biomedical engineering, or a related scientific field). Degree must have been received within the past five years, or be currently pursuing.

Preferred skills:

- Comfortable researching independently and maintaining high initiative and critical thinking skills with attention to detail.
- Ability to contribute to multi-disciplinary teams and groups to resolve difficult or controversial research questions.
- Excellent scientific writing and communication skills in English.

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** (10 👁)
  - **Engineering** (3 👁)
  - **Environmental and Marine Sciences** (2 👁)
  - **Life Health and Medical Sciences** (25 👁)
- **Veteran Status:** Veterans Preference, degree received within the last 120 month(s).

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.