

Opportunity Title: FDA Data Mining for the Development of New Toxicological Risk Assessment Approaches for Medical Devices

Opportunity Reference Code: FDA-CDRH-2024-0018

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

Reference Code FDA-CDRH-2024-0018

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.

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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), Food and Drug Administration (FDA), located at Silver Spring, Maryland, **or may be remote**.

Research Project: The Biocompatibility/Toxicology program in the FDA Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Laboratories (OSEL) has an opening in Silver Spring, MD for a full-time early career scientist or engineer with a strong background in data science and/or computer programming with some understanding of chemistry and biology. The fellowship involves developing a process or an application that will survey existing FDA databases for data from medical device submissions to develop Regulatory Science Tools (RST) to reduce or replace animal use in the biocompatibility evaluation of medical devices. The data gathered will be analyzed and presented through different platforms (Smartsheet, PowerPoint, etc.).

The fellowship involves 100% computational research to survey submissions across all medical device types. There is opportunity for this role to be partially or fully remote.

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

Anticipated Appointment Start Date: October 15, 2024. Start date is flexible and will depend on a variety of factors.



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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 and Lawful Permanent Residents (LPR) only.

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 be currently pursuing or have received a bachelor's, master's, or

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doctoral degree in the one of the relevant fields (computer science, engineering, physics, or other relevant field). Degree must have been received within the past five years, or be currently pursuing.

Preferred skills:

- Those with a life sciences degree (e.g., biology, chemistry) with relevant experience (e.g., using data analytics in their thesis work) will also be considered.
- Experience using python to search databases to gather data
- Experience reviewing, analyzing, and using data or other information to advance and convey information
- Comfortable working independently and maintaining high initiative and critical thinking skills with attention to detail
- Ability to contribute to and help coordinate multi-disciplinary teams and work groups to resolve difficult or controversial research questions
- Excellent written and spoken English.

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **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** ([7](#))
 - **Engineering** ([4](#))
 - **Life Health and Medical Sciences** ([35](#))
 - **Mathematics and Statistics** ([5](#))
 - **Physics** ([1](#))
- **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.