Opportunity Title: FDA Fellowship on TEEM Calculator Web Tool Development to Support Toxicological Risk Assessment of Medical Devices
Opportunity Reference Code: FDA-CDRH-2023-13

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

Reference Code FDA-CDRH-2023-13

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 8/11/2023 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 Science and Engineering Laboratories (OSEL), within the Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA) located in Silver Spring, Maryland.

Medical device manufacturers and federal regulators use toxicological risk assessments to analyze the biocompatibility risk of patient exposure to potentially harmful levels of chemical extractables that may be released from a medical device (e.g., implants) during clinical use in or by patients. Recently, we completed phase 1 of a project leading to the development and debugging of a web-based app, the TEEM Calculator Tool, that calculates key parameters used for toxicological risk assessments, based on device and chemical extractables specific information. The calculations are provided in an output file. The goal of this project is to further debug and refine the TEEM Calculator Tool while also developing a database that extracts the medical device and chemical specific information from the TEEM Calculator Tool output to be used by FDA regulators.
Under the guidance of a mentor, the participant will gain hands-on experience through the opportunity to apply programming and database development skills learned during their academic training, as well as learn new programming skills to refine the TEEM Calculator Tool web app and collaborate on a database of medical device and chemical specific information to be extracted from the TEEM Calculator Tool output. This experience provides the ORISE fellow with the opportunity to gain real-word experience in developing regulatory science tools to address rising concerns when evaluating the biocompatibility risk of medical devices. In

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Anticipated Appointment Start Date: July 24, 2023; start date is flexible

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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 6 months, 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 part-time (20 hours per week) on-site for laboratory research at the 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 (OPM) 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 should have received a bachelor's, master's or doctoral degree in one of the relevant

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fields. Degree must have been received within the past five years.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (5 👁)
- **Veteran Status:** Veterans Preference, degree received within the last 120 month(s).

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.) I have read the FDA Ethics Requirements.