

Opportunity Title: FDA Analytical Chemist for Medical Device Research

Postdoctoral Fellowship

Opportunity Reference Code: FDA-CDRH-2023-03

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

Reference Code FDA-CDRH-2023-03

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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 4/6/2023 3:00:00 PM Eastern Time Zone

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

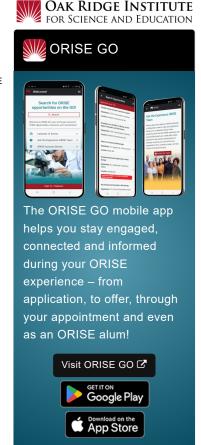
A research opportunity is available in the Division of Biology, Chemistry, and Material Sciences (DBCMS) Office of Science and Engineering Laboratories (OSEL) within the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

The fellow will perform studies related to analysis of extractable and leachable chemicals from materials used in medical devices. Tasks will include method development and validation for extraction, identification, quantification of substances contained in polymeric and other materials to support CDRH's regulatory mission.

Participant will gain hands-on experience in sample extraction, advanced mass spectrometry instrument operation and maintenance, as well as the corresponding data processing and analysis. Participant will have the opportunity to present their results at conferences and publish their findings in peer reviewed publications. In addition, participants will have the opportunity to learn about the regulatory practices and collaborate with different FDA centers and outside agencies. As a result of this training the participant will improve their skills in conducting independent research, communication and collaborations.

Anticipated Appointment Start Date: April 1, 2023; start date is flexible

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



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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 on-site for laboratory research 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-

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 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 doctoral degree in one of the relevant fields (e.g. Analytical Chemistry, Chemical Engineering), or be currently pursuing the degree with completion before the appointment start date. Degree must have been received within the past five years.

Preferred Skills:

- · Hands-on experience in following techniques including but not limited to: sample preparation techniques (e.g., solid phase extraction, liquidliquid extraction, and solid phase microextraction), liquid chromatography mass spectrometry (LC-MS), and gas chromatography mass spectrometry (GC-MS).
- · Experience in quantification of small molecules and polymers
- Experience in data analysis software packages, database generation and statistical evaluation
- An understanding of extractables studies and non-targeted analysis
- Good writing and communication skills

Eligibility Requirements

- Degree: Doctoral Degree received within the last 60 months or currently pursuing.
- Discipline(s):
 - Chemistry and Materials Sciences (12. •)
 - Engineering (3_
 - Environmental and Marine Sciences (1...)
 - Life Health and Medical Sciences (2.

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.)

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