

Department of Health and Human Services (HHS) Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Office of Science and Engineering Laboratories (OSEL)

Position Title: Toxicologist/Analytical Chemist (Staff Fellow)

Location: Silver Spring, Maryland

Application Period: April 27, 2022 – May 27, 2022

Salary Range: \$106,823-164,102 (commensurate with education and experience)

Position Information: Full-Time – appointment term of 3 years, with possibility of being extended.

Who may be considered: US Citizens; Permanent Residents; and Non-Citizens

Introduction: The Food and Drug Administration (FDA) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective. The mission of CDRH is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States. OSEL is dedicated to promoting patient access to innovation, safe and effective medical devices through best-in-the-world regulatory science. The Division of Biology, Chemistry and Materials Science (DBCMS) within CDRH's OSEL, promotes and protects public health by identifying logical and physio-chemical mechanisms of interaction between the human body and medical devices, the end goal being safety and effectiveness thereof.

Position Summary: The DBCMS has an opening for a staff fellow/engineer with expertise in Analytical Chemistry and Toxicological Risk Assessment. We are seeking a candidate with laboratory and hands on experience in analytical chemistry techniques such as gas chromatography-mass spectrometry (GC/MS), liquid chromatography-mass spectrometry (LC/MS), high-performance liquid chromatography (HPLC), and inductively coupled plasma mass spectrometry (ICP/MS) and their application in chemical characterization. The candidates must also be able to demonstrate mastery of principles, practices, and theories in the field of Toxicology and Toxicological Risk Assessment that enables the incumbent to serve as a technical authority in the scientific analysis of the safety and effectiveness of medical devices

The staff fellow will also serve as a technical authority in the scientific analysis of the safety and effectiveness of medical devices; provide an authoritative analysis of scientific data submitted to the Agency; and provide - policy or consulting support for reviews of new medical devices in the area chemical characterization. The successful candidate will generate written technical and scientific documents for peer-reviewed publications and consulting support activities.

Educational Requirements: Applicants must possess a Ph.D. or equivalent degree in chemistry, toxicology, biomedical engineering, chemical engineering, or a related scientific field. Applicants who have completed part or all their education outside the US must have their foreign education evaluated by an accredited organization to ensure that the foreign education is comparable to education received in accredited educational institutions in the US. This evaluation must also be provided by midnight Eastern Time on the closing date of this vacancy announcement. For more information on Foreign Education verification, visit the U.S. Department of Education. Another listing of services that can perform this evaluation is available at the National Association of Credential Evaluation Services (NACES) website.



Qualifications: Please document knowledge, skills, and abilities relevant to each area described below:

- Ph.D. from an accredited university in toxicology, chemistry, biomedical engineering, or a related scientific field.
- At least three years of experience planning and conducting research in one or more of the following areas: toxicological risk assessment, chemical characterization and method development, quantification methods in chemical characterization, and chemical equivalence studies related to medical devices.
- Knowledge of ISO 10993-18 and other medical device related standards, working experience preferred.
- Knowledge of the scientific principles and practices associated with designing experiments to address research topics in chemical characterization, material science and data science.
- Experience with accurate quantification of compounds, use of chemical equivalence studies as it relates to materials and manufacturing of materials, and use of chemical characterization methods and data science methodology as it relates to medical devices.
- Demonstration of a track record of independent work is required.
- Demonstrated ability to participate in and contribute to multi-disciplinary teams and work groups to resolve difficult or controversial research questions.
- Excellent scientific writing and communication skills.

How to Apply: Prior to applying, please see the following instructions:

- Documents to submit: electronic resume or curriculum vitae, cover letter describing why you are uniquely qualified for this, and copy of transcripts
- Compile all applicant documents into one combined document (i.e., Adobe PDF)
- Include Job Reference code "2020-OSEL-DBCMS-004" in the email subject line.
- Email applicant package to: CDRH-OSEL-Opportunities@fda.hhs.gov.

Additional Announcement Information

- 1. Security and Background Requirements: All candidates must meet applicable security requirements which include a background check and a minimum of 3 out of the past 5 years' residency status in the US. If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security reinvestigation or supplemental investigation may be required at a later time. Applicants are also advised that all information concerning qualifications is subject to investigation. False representation may be grounds for non-consideration, non-selection, or appropriate disciplinary action.
- **2. Benefits:** The Federal Government offers a comprehensive benefits package. Explore the major benefits offered to most Federal employees at https://www.usa.gov/benefits-for-federal-employees
- **3.** For more information about Office of Science and Engineering Laboratories (OSEL) at FDA/CDRH: https://www.fda.gov/about-fda/cdrh-offices/office-science-and-engineering-laboratories.
- **4.** Travel, transportation and relocation expenses will **not** be paid.