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 - (Staff Fellow)

Location: Silver Spring, Maryland, FDA Headquarters, White Oak Campus

Application Period: Friday, February 11, 2022, through Friday, March 11, 2022

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

Position Information: Full-Time – Appointment term of three (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/OSEL promotes and protects public health by identifying mechanisms of interaction between the human body and medical devices to help support safety and effectiveness of medical devices.

Position Summary: DBCMS is now accepting applications for one or more Staff Fellows who have experience as a Toxicologist, Toxicology Risk Assessor, Biomedical Engineer, or a Biologist. Candidates must be able to demonstrate mastery of principles, practices, and theories in the field of Toxicology and Toxicology Risk Assessment that enables the incumbent to serve as a technical authority in the scientific analysis of the safety and effectiveness of medical devices. Additionally, candidates must be able to provide authoritative analysis of scientific data submitted to the Agency and develop or qualify innovative tools and approaches to facilitate scientific evaluations required for medical device review. The position involves approximately 50% laboratory research and 50% regulatory review and consultative support for applications of medical devices.

Major Duties and Responsibilities:

- Lead and conduct regulatory science research to a) develop predictive toxicology and risk assessment tools/approaches focused on *in vitro* cellular and computational methodologies to predict the toxicity of compounds associated with medical device materials, including polymeric chemical constituents and their metabolic byproducts, and metallic species, and b) develop and incorporate alternative *in vitro* or *in silico* test methods and procedures that advance hazard and risk assessments with a focus on medical devices.
- Design, implement, and conduct OSEL-prioritized research on adverse responses and relevant mechanism(s) of medical device material/tissue interactions associated with extractables and leachables

from polymers and metal alloys using research approaches within the disciplines of Toxicology, Immunotoxicology, Genetic Toxicology, and Biomedical Engineering.
- Conduct multiple, concurrent health risk assessments for medical device materials, extracts, and leachables
- Review risk assessments and biocompatibility test data from sponsor submissions and makes recommendations to Division leadership and regulatory review staff pertaining to findings.
- Serve on FDA taskforces/working groups, as needed.
- Produce written products of high quality, including peer-reviewed publications that receive wide distribution within the scientific, healthcare, and medical device communities.

Educational Requirements: Applicants must possess a PhD, or equivalent science degree (e.g., ScD, DVM) in Toxicology, Pharmacology, Biomedical Engineering, Immunology, Biology, Chemistry, or comparable biomedical disciplines. 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.

Desirable Education and Experience: Please document knowledge, skills, and abilities relevant to each area described below:
- Ph.D. or equivalent degree from an accredited university in Toxicology, Pharmacology, Biomedical Engineering, Immunology, Biology, Chemistry, or comparable biomedical disciplines. Postdoctoral research experience is preferred.
- A minimum of five (5) years of experience in conducting research to a) develop predictive toxicology and human health risk assessment tools/approaches focused on in vitro cellular and computational methodologies, and/or b) assess adverse responses and relevant mechanism(s) of material/tissue interactions associated with extractables and leachables from polymers and metal alloys using research approaches within the disciplines of Toxicology, Immunotoxicology, Genetic Toxicology, and Biomedical Engineering. Experience related to medical devices is highly desirable.
- Demonstrated
- A minimum of five (5) years of experience conducting and three (3) to five (5) years of leadership experience in providing technical direction of assessments of risks to human health from exposure to chemicals, chemical hazard identification, and selection of studies for quantitative dose-response and exposure assessments.
- Evidence of a strong track record of research and peer-reviewed publications in chemical hazard identification, toxicology, biomedical engineering, and risk assessment.
- Knowledge of the scientific principles, theories and practices associated with the discipline of Toxicology and Biomedical Engineering and the assessment of risks to human health posed by chemicals, extractables, and leachables.
- Ability to participate in and contribute to Agency, Center, Office, or other professional organizations' task forces/work groups and teams.

- Demonstrated ability to effectively communicate, both in oral and written formats, to a variety of audiences (e.g., scientific, management, policy makers) the scientific basis, methods, data, and conclusions of scientific analyses.

How to Apply: Submit an electronic resume or curriculum vitae, cover letter containing describing why you are uniquely qualified for this position, and a copy of unofficial transcripts all in **one** document (**Adobe PDF**) to CDRH-OSEL-Opportunities@fda.hhs.gov, with Job Reference code ***"2020-OSEL-DBCMS-002"*** in the subject line. Applications will be accepted through **March 11, 2022.**

Additional Announcement Information

1. **COVID-19:** Due to COVID-19, the Agency is currently in an expanded telework posture. If selected, you may be expected to temporarily telework, even if your home is located outside the local commuting area. Once employees are permitted to return to the office, you will be expected to report to the duty station listed on this announcement within 45 days. At that time, you may be eligible to request to continue to telework one or more days a pay period depending upon the terms of the agency's telework policy. To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Safer Federal Workforce Task Force guidance on other Federal agency safety protocols based on vaccination status—including guidance on protocols related to masking, distancing, travel, testing, and quarantine—remains in effect.
2. **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 U.S. 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.
3. **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
4. 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.
5. Travel, transportation, and relocation expenses **will not** be paid.