FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Staff Fellow (Toxicologist-Biocompatibility)

INTRODUCTION: The Center for Devices and Radiological Health (CDRH or Center), the medical devices scientific and regulatory arm of the U.S. Food and Drug Administration (FDA), welcomes applications from scientists and engineers to join our scientific and regulatory research teams, as Staff Fellows, in the Office of Science and Engineering Laboratories (OSEL). These positions are located in OSEL's Division of Biology, Chemistry, and Materials Science (DBCMS or Division), which focuses on a host of public health concerns in the areas of biocompatibility and toxicology, sterility and infection control, materials chemistry and performance, and nanotechnology.

POSITION SUMMARY: DBCMS is recruiting Staff Fellows who have significant experience as Toxicologists, Toxicology Risk Assessors, Biomedical Engineers, or Biologists. We are seeking experienced scientists who are able to demonstrate mastery of principles, practices, and theories in the fields of Toxicology and Toxicology Risk Assessment, providing you with the credentials and expertise to serve as technical authorities in the scientific analysis of the safety and effectiveness of medical devices and products. Additionally, you will offer 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.

DUTIES / RESPONSIBILITIES: As Staff Fellow, you will perform the following duties:

- 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 and product communities.

PROFESSIONAL EXPERIENCE / KEY REQUIREMENTS: To qualify for this position, you must demonstrate in your resume the necessary experience for this position, which is equivalent to the following:

- 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.

- 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.

BASIC QUALIFCATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: Toxicology (0415), Biology (0401), Microbiology (0403), Pharmacology (0405), Bioengineering and Biomedical Engineering (0858), Chemical Engineering (0893), Chemistry (1320).

ADDITIONAL QUALIFCATIONS: To qualify as a Staff Fellow, you must: be a US Citizen, Permanent Resident, or Non-Citizen with residency status in the U.S., three (3) out of the last five (5) years; possess a doctoral-level degree from an accredited institution of higher learning, including: Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or other research doctoral-degree widely recognized in U.S. academe as equivalent to a Ph.D.. (*In limited instances non-doctoral candidates, and/or candidates with less experience may be acceptable*).

FOREIGN EDUCATION: Candidates who have completed part or all of their education outside the United States must, in order to meet qualification requirements, have their foreign education evaluated by an accredited organization to ensure the foreign education is comparable to education received in the United States. It is the responsibility of the candidate or employee to provide written proof of her/his foreign education accreditation prior to appointment or placement in a different occupational series from which placed. *For further information, visit the U.S. Department of Education - Foreign Education Evaluation.*

POSITON LEVELS: These Staff Fellow positions will be filled at the equivalent pay grades of the General Schedule (GS) 13 and 14. Similar to the GS, specific duties may vary by position level. For additional salary information, click here.

CONDITIONS OF EMPLOYMENT

- One-year probationary period may be required.
- This position is for a **three-year** appointment and will be filled through FDA's Staff Fellowship Program
- Background and/or Security investigation required.
- Applicants who are U.S. Citizens and born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption.
- This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For additional information, please visit the FDA Ethics and Integrity Office.
- All candidates must meet applicable security requirements which include a background check and a minimum of three (3) out of the past five (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.

- 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. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

LOCATIONS: FDA's White Oak Campus in Silver Spring, Maryland

SALARY: Salary starts at $106,823.00 and is commensurate with education and experience

BENEFITS: A comprehensive benefits package is offered to most Federal employees. For additional benefit information click here.

HOW TO APPLY: Prior to applying, please see the following instructions:

- Submit an electronic resume or curriculum vitae and a cover letter describing why you are uniquely qualified for this job.
- Include Job Reference code ***"CDRH-OSEL-DBCMS-M4-176"*** in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications with supporting documentation will be accepted through **March 31, 2023.**
- Visit CDRH Jobs to see additional opportunities.
- Contact Denise Townsend for questions: Denise.Townsend@fda.hhs.gov

The United States Government equal opportunity employer and does not discriminate on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service or other non-merit factor.