

Staff Fellow – (Toxicologist/Analytical Chemist)

INTRODUCTION: The Center for Devices and Radiological Health ([CDRH](#)), a major regulatory component of the Food and Drug Administration ([FDA](#)) and the Department of Health and Human Services, is inviting applications for a Staff Fellow (Toxicologist/Analytical Chemist) in the Division of Biology, Chemistry, and Materials Science ([DBCMS](#)), Office of Science and Engineering Laboratories ([OSEL](#)). The Division is comprised of wide-ranging expertise to address a host of issues stemming from chemical characterization of device materials, material performance, sterilization, infection control, biocompatibility and toxicology.

POSITION SUMMARY: DBCMS is recruiting a Staff Fellow with laboratory and hands on experience in Analytical Chemistry and Toxicological Risk Assessment. The candidates will apply mastery of principles, practices, and theories in the field of Toxicology and Toxicological Risk Assessment to serve as technical authorities in the scientific analysis of the safety and effectiveness of medical devices.

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

- 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.
- Generate written technical and scientific documents for peer-reviewed publications and consulting support activities.
- Utilize expert scientific and technical knowledge to serve as an advisor or consultant on regulations and policies involving complex and high priority matters affecting the regulation of new medical devices.
- Prepare oral and written communications of review recommendations.
- Effectively communicate within FDA, with device manufacturers, and with other public health stakeholders.

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:

- 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
- 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.

BASIC QUALIFICATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: [Toxicology \(0415\)](#), [Bioengineering and Biomedical Engineering \(0858\)](#), [Chemical Engineering \(0893\)](#), [Chemistry \(1320\)](#).

ADDITIONAL QUALIFICATIONS: 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](#).

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 post-PhD experience

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 "**2020-OSEL-DBCMS-004**" in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications with all supporting documentation will be accepted through **November 30, 2022**

- 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.