

Staff Fellow (Analytical Chemists) - Multiple Vacancies

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 (Biochemistry/Chemistry/Microbiology) in the Division of Biology, Chemistry, and Materials Science ([DBCMS](#)), Office of Science and Engineering Laboratories ([OSEL](#)). The division comprises wide-ranging expertise to address a host of issues stemming from molecular-level interactions between the human body and medical devices or radiation-emitting products.

POSITION SUMMARY: DBCMS is recruiting Staff Fellows with experience in analytical chemistry techniques such as liquid and/or gas chromatography-mass spectrometry (LC-MS, GC-MS), high-performance liquid chromatography (HPLC), and inductively coupled plasma mass spectrometry (ICP-MS) and their application to material / chemical characterization.

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

- Conduct laboratory research to develop new and innovative approaches to scientific testing in analytical chemistry.
- 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 develop new and innovative approaches to scientific testing required for medical device reviews by FDA.
- 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 in the areas of material science and chemical characterization.
- Generate written technical and scientific documents for peer-reviewed publications and consulting support activities.
- Prepare oral and written communications of review recommendations.

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

- 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.

Additionally, you must demonstrate in your resume the necessary experience, which is equivalent to the following for one or more of the below specific positions:

Position 1 – Analytical Chemist:

- Demonstrated independent and collaborative experience planning and conducting research in one or more of the following areas: chemical characterization of medical devices and analytical method development, quantitative analysis, chemical equivalence studies related to medical devices and data science/chemometrics experience
- Experience reviewing, analyzing, and using scientific data or other information to advance and convey understanding of chemical characterization in medical device examination, including understanding ISO 10993 – part 18 as well as use and understanding all other medical device related standards.
- Knowledge of the scientific principles and practices associated with designing experiments to address research topics in chemical characterization materials and data science.

Position 2 – Analytical Chemist:

- Demonstrated independent and collaborative experience planning and conducting research in one or more of the following areas: chemical characterization and method development emphasizing structure elucidation along with non-targeted analysis, development of computational tools and data science,

quantification methods in chemical characterization, and chemical equivalence studies related to medical devices.

- Experience reviewing, analyzing, and using scientific data or other information to advance and convey understanding of material science and chemical characterization in medical device examination, including understanding ISO 10993 – part 18 as well as use and understanding all other medical device related standards such as ISO 18562, ISO 11979 and relevant USP standards such as USP <1663>.
- Knowledge of the scientific principles and practices associated with designing experiments to address research topics in chemical characterization materials and data science. In addition, experience in non-targeted analysis and omics research will be plus.

Position 3 – Analytical Chemist:

- Experience reviewing, analyzing, and using scientific data or other information to advance and convey understanding of material science and chemical characterization in medical device examination, including understanding ISO 10993 – part 18 as well as use and understanding all other medical device related standards such as ISO 18562, ISO 11979 and relevant USP standards such as USP <1663>.
- Understanding of toxicological principles and how to apply chemical characterization to perform toxicological risk assessment.
- Understanding of medical device product development, device material sourcing and current biocompatibility challenges in assessing new devices.
- Knowledge of the scientific principles and practices associated with designing experiments to address research topics in chemical characterization materials and data science.
- Experience in leading projects and having project management skills.

Position 4 – Analytical Chemist

- Must have at least 3 years of postgraduate experience in planning and conducting research in microbiological identification or characterization chemical characterization of medical device materials.
- Must have experience analyzing and identifying microorganisms using MALDI-TOF in research or clinical settings.
- Must have experience in analytical chemistry techniques such as liquid and/or gas chromatography-mass spectrometry (LC-MS, GC-MS), high-performance liquid chromatography (HPLC), and inductively coupled plasma mass spectrometry (ICP-MS) and their application to material / chemical characterization.
- Experience reviewing, analyzing, and using scientific data or other information to advance and convey understanding of chemical characterization in medical device examination, including understanding ISO 10993 – part 18 as well as use and understanding all other medical device related standards.
- Knowledge of the scientific principles and practices associated with designing experiments to address research topics in microbiology, chemical characterization materials and data science.

BASIC QUALIFICATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: [Biology \(0401\)](#), [Microbiology \(0403\)](#), [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*).

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](#).

LOCATIONS: [FDA's White Oak Campus](#) in Silver Spring, Maryland

SALARY: Salary is commensurate with education and 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 "**CDRH-OSEL-DBCMS-053**" in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications and all supporting documentation will be accepted through **December 5, 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.