

Staff Fellow (Biochemistry / Chemistry / Microbiology)

INTRODUCTION: The Center for Devices and Radiological Health (<u>CDRH</u>), a major regulatory component of the Food and Drug Administration (<u>FDA</u>) 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 (<u>DBCMS</u>), Office of Science and Engineering Laboratories (<u>OSEL</u>). The division comprises 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 experience in biochemical, chemical and/or microbiological techniques relating to biofilm formation and characterization, disinfection and sterilization of medical devices to support the Sterility and Infection Control Program.

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 develop new and innovative approaches to scientific testing required for medical device reviews by FDA.
- 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 planning and conducting research using methods of analyte detection (e.g., protein concentration assays, residual moisture detection, hemoglobin detection assays) and MALDI-TOF in at least one of the following areas sterilization, reprocessing, biofilm formation, medical device associated infections, and/or bacterial-material interactions.
- Experience reviewing, analyzing, and using scientific data or other information to advance and convey understanding of biochemical and/or microbiological techniques including: analytical methods for analyte detection, MALDI-TOF, sterilization, medical device reprocessing (including cleaning and disinfection), antimicrobial technologies, and/or biofilms.
- Ability to develop project plans and manage timely execution of project deliverables and timelines.
- Demonstrated ability to participate in and contribute to multi-disciplinary teams and work groups to resolve difficult or controversial research questions.
- Demonstrated experience with principles and practices of sterilization and infection control associated with medical devices.

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

ADDITIONAL QUALIFCATIONS: To qualify as a Staff Fellow, you must: be a US Citizen, Permanent U.S. Food & Drug Administration 10903 New Hampshire Avenue



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 <u>Selective Service System</u> 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-026" in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications and all supporting documentation will be accepted through July 11, 2022.
- Visit CDRH Jobs to see additional opportunities.

HHS/FDA is an equal opportunity and affirmative action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or protected veteran status.









