U.S. FOOD & DRUG ADMINISTRATION

Staff Fellow (Biofilms-Medical Device Related Infections)

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 Fellow with experience in biofilm development in the context of medical device associated infections to support the Sterility and Infection Control Program. You will apply your experience in biofilm growth methods, biofilm detection and characterization, or biochemical markers of biofilm and biofouling.

DUTIES / RESPONSIBILITIES: As a 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.
- 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 utilizing microbiological and analytical methods to evaluate biofilm formation in at least one of the following areas medical device-associated infections, sterilization, reprocessing and/or bacterial-material interactions.
- Experience including, but not limited to, biofilm growth methods, biofilm detection and characterization, MALDI-TOF or biochemical markers of biofilm and biofouling.
- Demonstrated success in developing novel test methodologies to study biofilm development on medical devices or materials and evidence of their utilization to advance product development.
- Experience engaging with customer and stakeholders to evaluate unmet needs/challenges, identify high impact opportunities, mitigate risk and prioritize resources/budget and plan and milestones/deliverables for a complex program -in an industrial or academia setting.
- Demonstrated success in developing strong academic collaborations leading to the development of novel methodologies to study biofilm development/characterizationon medical devices and/or materials.
- Ability to develop program plans and manage timely execution of project deliverables and timelines.

BASIC QUALIFCATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: Biology (0401), Microbiology (0403), 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*).

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-001"*** 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov