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

Staff Fellow (Biofilms-Medical Device Related Infections)

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 Sterility and Infection Control Program, as Staff Fellows, in the Office of Science and Engineering Laboratories (OSEL). This position is 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 with strong backgrounds in biochemical, chemical, and/or microbiological techniques and who have significant relevant experience in biofilm development in the context of medical device associated infections. Required experience may include, but is not limited to, biofilm growth methods, biofilm detection and characterization, or biochemical markers of biofilm and biofouling. This position involves laboratory research, policy interpretation, and consultation support for our medical device review teams, regarding the evaluation of novel devices regulated by the Center and Agency. As an integral member of the Sterility and Infection Control Program, you will develop new and innovative approaches to scientific testing of new and emerging medical devices and products regulated by the FDA.

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

- Serve as a technical authority in the scientific analysis of the safety, effectiveness, reliability, and performance of medical devices and products regulated the FDA.
- Provide an authoritative analysis of scientific and technical data submitted to the Agency for review.
- Generate written technical and scientific documents for peer-reviewed publications and consulting support activities.
- Utilize expert scientific and vast technical knowledge to serve as an advisor and consultant on regulations and policies involving highly complex and high priority matters affecting the regulation of new medical devices.
- Draft and share recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, and reliability concerns, with Division and Office leadership.

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. from an accredited university in Biology, Biochemistry, Chemistry, Microbiology, Biomedical Engineering, Chemical Engineering, or related scientific fields.
- A minimum of seven (7) years of experience, after receiving Ph.D., in planning and conducting research utilizing microbiological and bioanalytical methods to evaluate biofilm formation in at least one of the following areas medical device-associated infections, sterilization, reprocessing and/or bacterial-biomaterial interactions.
- Extensive experience Drip Flow Reactors, biofilm growth methods, biofilm detection and characterization, and biochemical markers of biofilm and biofouling.
- Extensive knowledge and expertise in growing and evaluating biofilms on medical device materials including polymers and metals are required.
- Documented 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 in engaging with customers and stakeholders to evaluate unmet needs and challenges, identifying high impact opportunities, mitigating risk and prioritizing resources and budgets for complex programs in industrial or academia settings.

- Demonstrated success in developing strong academic collaborations leading to the development of novel methodologies to study biofilm development on medical devices and/or materials.
- Demonstrated ability to develop program 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.
- Excellent scientific writing and communication skills.

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*).

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.

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- 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 $124,626.00 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-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 **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.