Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Science and Engineering Laboratories (OSEL)
Division of Biology, Chemistry, and Materials Science (DBCMS)

Position(s): Research Scientist/Engineer

Series: The position may be filled by candidates from the following occupational series: Biologist (0401), Microbiologist (0403), Chemist (1320), Chemical Engineer (0893), General Engineer (0801), Material Engineer (0806), Mechanical Engineer (0830), and Biomedical Engineer (0858)

Location(s): Silver Spring, Maryland, FDA headquarters, White Oak Campus

Travel Requirements: This position may require up to 25% travel.

Application Period: September 15, 2022 – October 14, 2022

Salary: Salary starts $126,233.00 and is commensurate with experience

Conditions of Employment: United States Citizenship is required

Special Notes: This position is being filled under an excepted hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of the authority. Additional information on 21st Century Cures Act can be found here.

Introduction: The Center for Devices and Radiological Health (CDRH or Center) assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. The Office of Science and Engineering Laboratories (OSEL or Office), which is comprised of multidisciplinary scientists and engineers from a wide array of specializations, works to advance the mission of CDRH by promoting innovation, through experimentation and research to support the development of new and emerging diagnostic, lifesaving, and life-sustaining medical devices.

The Division of Biology, Chemistry, and Materials Science (DBCMS or Division), where this position is located, develops regulatory science tools and innovative testing methodologies to support the evaluation and better understanding the biological and physiochemical effects of medical devices and products on and in the human body. DBCMS' work facilitates the evaluation of the safety, effectiveness, performance, and reliability of medical devices and products throughout the total product life cycle.

Position Summary: CDRH is seeking a senior level scientific and regulatory expert to serve as a technical expert and advisor to the Division Director for the Sterility and Infection Regulatory Science Program. This is a high priority and highly visible Program in OSEL and addresses key focus areas on advancing regulatory science in novel sterilization modalities, reprocessing of reusable

medical devices, and anti-microbial device/product technologies to reduce health care associated infections. This Program delivers regulatory science tools facilitating device innovation and creating consistency in device testing methods where existing standards and guidance do not exist. You will be responsible for providing strategic, technical, and programmatic leadership, and exercise sound scientific and evidenced-based technical judgment in all areas of sterility and infection control regarding medical devices and products, to include the development of novel theories and methods that will be used by other researchers and medical device manufacturers.

Duties/Responsibilities: As the DBCMS Research Scientist/Engineer, you will:

- Utilize expert scientific, research, and technical knowledge and vast regulatory expertise to serve as an authoritative and principal advisor to the DBCMS Director, as well as serving as an expert resource for the Division, Office, and Center in the areas of sterility and infection control of materials and medical devices.
- Serve as the primary investigator in areas of sterilization reprocessing and device associated infections, but not limited to reusable medical devices, antimicrobial technologies, and biofilms within CDRH.
- Provide expert technical consultation to the Office of Product Evaluation and Quality (OPEQ) regarding pre-market medical device and product applications, as well as reported post-market adverse events and concerns associated with sterility, reprocessing, and device associated infections.
- Serve an authoritative voice on scientific matters pertaining to the development and validation of devices and processes associated with reusable medical devices, test methods, and models to evaluate risk of device associated infections, material modifications, and device technologies and interventions to reduce risk of infections.
- Provides expert consultation and guidance in the review of microbiology, material, and device performance, sterilization, and reprocessing in pre-market and post-market submissions, and participates in policy drafting and decisions through the creation and review of FDA guidance documents and consensus standards.
- Analyze and interpret data to identify safety issues related to material and device performance, and the sterilization and reprocessing of medical devices that may result in device and/or product associated infections.
- Contribute significantly to developing the regulatory science strategy for the Sterility and Infection Control Program through contributions in peer-reviewed scientific journals and by leading and participating, regularly, in local and national meetings regarding the sterilization and reprocessing of medical devices and products.
- Forge mutually beneficial formal partnerships with medical device manufacturers, professional scientific organizations, the healthcare community, patient advocacy groups, academia, and other federal, state, and local stakeholders to provide research direction to address specific technical issues, which may influence decisions, Agency guidance, and changes in policy and standards.
- Engage with internal and external stakeholders and stays abreast of new technologies rapidly entering the medical devices markets relevant to sterility and infection control, including novel device anti-microbial technologies, test methods, and models to evaluate the safety and efficacy of materials, devices, and processes that may impact device related infections.
- Collaborate with colleagues across the Division, Office, and Center to develop of new guidance documents and procedures regarding the regulatory and scientific review of in-scope medical devices and products.
- Represent the Center and Agency at meetings, discussions, advisory panels, and conferences involving officials from the Department and other Federal, state, and local government agencies, foreign governments, and international agencies, scientific laboratories and institutes involved in

biomedical engineering and scientific research, academic and medical communities, and representatives of regulated industry to present and explain DBCMS research and regulatory activities, plans, policies, and decisions.
- Draft and share recommendations of national public health significance, regarding the sterilization and reprocessing of medical devices and products, related device acquired infections, 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 qualifying experience for this position, which includes the following:
- Must have a minimum of ten (10) years of experience in sterilization, reprocessing, and novel technologies associated with the reduction of medical device and product related infections.
- Experience in medical device development process and validation of processes to reduce risk of device associated infections.
- Strong practicing knowledge of regulatory standards, guidance and test methods associated with medical device sterilization, reprocessing or requirements for medical devices with claims supporting anti-microbial efficacy.
- Must have a minimum of ten (10) years of experience in developing and leading large-scale, complex medical device related research or product development program utilizing stakeholder input, developing programmatic goals and objectives, budget, resources, and timelines.
- Experience leading multidisciplinary scientists in a medical device R&D setting or translational research program resulting in innovative solutions addressing complex issues in sterility and infection control related areas.
- Experience developing external collaborations with medical device industry, academic institutions, and regulatory agencies to drive development of methods, models and processes resulting in high impact solutions.
- Ability to analyze and interpret regulatory guidance to share expertise and advise executive-level leadership on highly complex and precedent setting public health matters.
- Demonstrated success in achieving product development or research goals through effective program management, risk mitigation and resource planning.

Desirable Education and Experience:
- Applicants with advanced degrees in Microbiology, Material Sciences, Engineering, Chemistry, or related fields.
- Demonstrated ability in providing technical expertise in an area of Sterility and Infection Control for medical device design, development, testing and/or regulatory science.
- Experience in medical device development and validation of processes to reduce risk of device associated infections.
- Demonstrated success in leading multi-disciplinary teams of scientists and engineers in the development and execution of strategies to address and overcome complex issues.
- Experience in interpreting and presenting complex information and concepts, in both written and oral formats to a broad audience
- Ability to work collaboratively with a diverse cadre of colleagues and stakeholders in a continuous quality improvement ecosystem, as well as prioritize initiatives, work projects, and make critical decisions.

Basic Qualifications:
Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Conditions of Employment:
- A probationary period may be required.
- Background and/or Security investigation required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption.
- This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. For additional information on the prohibited financial interests, visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply: Submit an electronic resume or curriculum vitae, a cover letter containing a brief summary of scientific accomplishments, and a copy of unofficial transcripts all in one document (**Adobe PDF**) to CDRHRecruitment@fda.hhs.gov, with Job Reference code ***"2022-OSEL-DBCMS-046"*** in the subject line. Applications will be accepted through **October 14, 2022.**

Equal Employment Opportunity Policy
The United States Government does not discriminate in employment 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.
- Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation Policy
Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.
A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits.

Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when:
- An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job.
- An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace.
- An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events.

You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis.

Learn more about disability employment and reasonable accommodations or how to contact an agency.

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