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): Assistant Director

Series: The position may be filled by candidates from the following occupational series: Biologist (0401), Microbiologist (0403), Toxicologist (0415), Physical Scientist (1301), Physicist (1310), Chemist (1320), 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: Wednesday, June 8, 2022, through Wednesday, June 22, 2022

Salary: Salary starts at $122,530.00 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. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

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) supports the mission of OSEL and the Center by developing regulatory science tools for evaluating and better understanding the biological and physiochemical effects of medical devices.. DBCMS' work facilitates the evaluation of the safety, effectiveness, and reliability of medical devices throughout the total product lifecycle.

Position Summary: CDRH is seeking an experienced scientific, technical, and regulatory expert to serve as an Assistant Director in DBCMS for Sterility and Infection Control Program. In this position, reporting directly to the DBCMS Director, you will be responsible for providing leadership, administrative management, and exercising sound scientific and evidenced-based technical judgment in the areas of sterility and infection control.

Duties/Responsibilities: As the DBCMS Assistant Director, you will:

- Utilize expert scientific knowledge and regulatory expertise to serve as an authoritative voice 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 medical device sterilization and infection control.
- Develop, implement, and manage the regulatory science strategy for the Sterility and Infection Control Program to ensure programmatic goals and objectives are met.
- Lead and manage an interdisciplinary team of scientists and engineers to execute the Sterility and Infection Control Program's research strategy and to provide technical expertise on complex regulatory submissions.
- Drive timely completion of program milestones and deliverables through effective resource management of staff to meet programmatic goals, objectives, and timelines.
- Engage with internal and external stakeholders and stays abreast of new and emerging technologies relevant to Sterility and Infection Control.
- Collaborate with colleagues across the Division and Office to assist in the development of new guidance documents, protocols, and procedures regarding the regulatory and scientific review of in-scope medical devices and products.
- Develop Division staff including relevant regulatory, technical and project management training for the purpose of supporting OSEL's mission and vision, Division's core expertise and execution excellence.
- In concert with the DBCMS Director, develop, coordinate, establish, and reinforce Division-wide policies, procedures, and programmatic norms rooted in science to assure medical products, especially those with novel and emerging technology, are safe, effective, reliable, and available.
- Provide expert technical advice, scientific leadership, guidance, and share research outcome information with Division staff to assist in the review and interpretation of scientific, theoretical, and reported data, to include safety, effectiveness, performance, and reliability concerns associated with regulated medical devices and products.
- Partner with Division leadership in the planning, organization, and the establishment or realignment of priorities, assignments, and work projects to advance new initiatives and to ensure the timely completion of regulatory and research commitments.
- Partner with the Division leadership to conduct regulatory science research, participate in pre- and post-market medical device review and surveillance activities, and provide training and educational opportunities to subordinate staff in the areas of sterility and infection control.
- 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, which may impact the availability of certain products due to safety, efficacy, and reliability concerns, with Division and Office leadership.

- 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.
- Create and sustain a strong and dynamic culture within the Team and Division including organizational agility, professional development, continuous process improvement, staff empowerment, and collaboration.

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:

- Biological, chemical, or materials science expertise in sterility and infection control, such as medical device associated infections, anti-microbial technologies, biofilms, device sterilization and/or reprocessing.
- Experience in leading and managing interdisciplinary teams of scientists and engineers in achieving organizational goals and objectives resulting in high impact to customers and stakeholders.
- Expertise in developing and implementing robust project management plans including resource management, project risk assessment and mitigation, stakeholder engagement, and evidence dissemination in support of scientific, public health and/or regulatory activities associated with FDA regulated medical devices and products.
- Experience in leading the identification of opportunities and gaps using customer and stakeholder feedback and its integration into the development of a product or research program.
- Expert knowledge of regulatory standards and guidance documents pertaining to medical device sterilization, reprocessing, and/or material performance.

Desirable Education and Experience:

- Applicants with advanced degrees in Microbiology, Chemistry, Engineering, Materials Science, or related fields.
- Demonstrated ability in providing technical expertise in an area of Sterility and Infection Control for medical device design, development, and testing or regulatory science.
- Effectively interpret and present complex information and concepts, in both written and oral formats.
- Ability to prioritize initiatives and work project 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, SF-50 (if applicable), and a copy of unofficial transcripts all in one document (**Adobe PDF**) to CDRHRecruitment@fda.hhs.gov, with Job Reference code ***"2020-OSEL-DBCMS-005"*** in the subject line. Applications will be accepted through **June 22, 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.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.
FDA is an equal opportunity employer