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), Physical Scientist (1301), Physicist (1310), Chemist (1320), General Engineer (0801), Material Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), 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: Friday, October 29, 2021, through Tuesday, November 23, 2021

Salary: Salary starts at $122,530.00 and is commensurate with experience

Conditions of Employment: U.S. Citizenship or permanent U.S. residency 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.

Within CDRH, 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. OSEL openly shares its data, technical expertise, and regulatory knowledge with internal and external stakeholders across the Center, Agency, Department of Health and Human Services, academia, industry, and standards organizations to support and ensure evidenced-based and transparent regulatory decision making, regarding medical devices throughout their total product lifecycle.

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, especially those radiation emitting diagnostic equipment, on the human body. DBCMS' work facilitates the evaluation of the safety, effectiveness, and reliability of medical devices and diagnostic equipment throughout the total product lifecycle.

Position Summary: CDRH is seeking an experienced and savvy scientific, technical, and regulatory expert to serve as an Assistant Director in DBCMS. In this position, reporting directly to the DBCMS Director, you will have the opportunity to advance the mission of OSEL and directly impact the health outcomes and the quality of life of the American people. You will be responsible for providing leadership, administrative management, and exercising sound scientific and evidenced-based technical judgment in the review of in-scope medical products throughout their total product lifecycle. Your critical regulatory work and the utilization of your vast scientific, research, and technical engineering expertise will assist the Director in advancing the mission of the Division, Office, and Center.

Supervisory Responsibilities:
You will assist the DBCMS Director in setting strategy, advancing initiatives, and ensuring the goals, priorities, and objectives of the Division align with those of OSEL, the Center, and the Agency. As an energetic and collaborative leader, you will assist in managing and growing a high-performing, multidisciplinary scientific, technical, and professional team, for optimal efficiency and performance, in support of advancing the technical proficiency of the Division and strategic vision of the Office. As such, you will evaluate the technical and managerial performance of your subordinate supervisors and devote at least 25 percent of your time towards coaching, mentoring, and supervising your leadership team.

Duties/Responsibilities:

As the DBCMS Assistant Director, you will:

- Utilize expert scientific, research, and technical engineering 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 and Office.
- Collaborate with colleagues across the Division and Office to assist in the development of new guidance documents and procedures regarding the regulatory and scientific review of in-scope medical devices and products.
- Ensure the uniform adoption, implementation, and consistent application of OSEL guidance, procedures, and policies, regarding the regulatory oversight of medical products within the scope of the Division are followed.
- 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 for patients and providers.
- Provide technical advice, scientific leadership, expert 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 and effectiveness concerns, associated with regulated medical devices and products.

- Collaborate with Division leadership in the planning, organizing, and the establishment or realignment of priorities, assignments, and work projects to advance new initiatives and/or the programmatic and regulatory objectives of the Division.
- 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 science and engineering.
- Represent the Division 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, the scientific, 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, biomedical and physics laboratories, professional scientific organizations, the healthcare community, patient advocacy groups, academia, and other federal, state, and local stakeholders.
- Creates and sustains a strong and dynamic culture within the Team and Division including organizational agility, a focus on continuous improvement, staff empowerment, and collaboration.
- Ensures the comprehensive support of product advisory panels, industry, and consultants and coordinates actions on classification actions, petitions, premarket notifications (510(k)s), premarket approval applications (PMAs), PDPs, De Novos, 513(g)s, and Investigational Device Exemptions (IDEs) with Center and Agency components or other organizations, when appropriate.

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:

- Experience in leading and managing multidisciplinary scientists, clinicians, and other regulatory professionals in large-scale science-based organizations.
- Ability to analyze and interpret complex research data, highly technical scientific information, regulatory policy, and guidance to share expertise and advise leadership and staff on uniquely complex and potential precedent setting public health matters.
- Leads the strategic achievement of organizational goals, evaluating organizational performance, and the development and implementation of targeted interventions to improve performance.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Skillful in effectively interpreting and presenting complex scientific, technical, and regulatory information and concepts, in both written and oral formats, to a variety of audiences.

Desirable Education and Experience:

- Applicants with advanced degrees in Biology, Chemistry, Engineering, Physics, Toxicology, or related fields.
- Prior experience in a scientific, regulatory, or medical device manufacturing setting.
- Ability to work collaboratively with a diverse cadre of colleagues and stakeholders in a continuous quality improvement ecosystem.

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 **November 23, 2021.**

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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