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 Imaging, Diagnostics, and Software Reliability (DIDSR)

Position(s): Deputy Division Director

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

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

Application Period: Thursday, October 21, 2021, through Friday, November 19, 2021

Salary: Salary starts at $144,128.00 and is commensurate with experience

Conditions of Employment: U.S. 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.

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 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 Imaging, Diagnostics, and Software Reliability (DIDSR) develops methods for evaluating the image quality of emerging imaging systems, develops methods for characterizing new medical image display devices, evaluates the dose reduction potential of new image reconstruction methods, and assesses the performance of Artificial Intelligence and Machine Learning algorithms. Additionally, DIDSR also develops state-of-the-art methods for the design of clinical trials involving imaging devices and the evaluation of clinical trial data to enable more efficient and effective

utilization of imaging data and the development of more powerful evidence-producing clinical studies.

Position Summary: CDRH is seeking an experienced and innovative scientific, technical, and regulatory expert to serve as Deputy Division Director of DIDSR. In this position, reporting directly to the DIDSR Director, you will have the opportunity to universally impact and improve the health outcomes and the quality of life of the American people through the advancement of diagnostic imaging medical devices. You will be responsible for providing leadership, administrative management, and exercising sound scientific and evidenced-based technical judgement in the review of in-scope medical products throughout their total product lifecycle. Your critical regulatory work and the utilization of your vast scientific and technical expertise will assist the Director in advancing the mission of the Division, Office, and Center.

Supervisory Responsibilities:
You will assist the DIDSR Director in setting strategy, advancing initiatives, and ensuring the goals, priorities, and objectives of the Division align with those of OSEL, the Center, and Agency. As a creative 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 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 DIDSR Deputy Division Director, you will:

- Utilize expert scientific and technical knowledge and vast regulatory expertise to serve as an authoritative and principal advisor to the DIDSR Director, as well as the OSEL Office Director, on matters involving diagnostic imaging medical devices, both novel and existing, encompassing the entire product lifecycle.
- Collaborate with colleagues across the Division and Office to develop new guidance documents, policies, and national and international consensus standards regarding the regulatory and scientific review of emerging diagnostic imaging and radiation emitting medical devices.
- 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 Office, are followed.
- In concert with the DIDSR Director and Office Director, develop, coordinate, and establish Division-wide policies, procedures, and programmatic norms rooted in science to assure diagnostic imaging medical products, especially those with novel and emerging technology, are safe, effective, reliable, and available for patients and providers.
- Provide technical advice, scientific leadership, and expert guidance in the review of policies and procedures associated with the regulated medical device imaging industry, regarding patient safety and product quality.
- Collaborate with the DIDSR Division Director and the OSEL Office Director 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 and Office.
- Partner with the Division Director to conduct regulatory science research, participate in pre- and post-market medical device review and surveillance activities, develop domestic and international

consensus standards, regulatory guidance, testing of forensic and regulatory samples, and provide training and educational programs in the area of science and engineering.
- Represent the Division, Office, 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, the scientific, academic, and medical communities, and representatives of regulated industry to present and explain DIDSR activities, plans, policies, and decisions.
- Advises the Division Director and Office leadership on the utilization of new and emerging technologies associated with artificial intelligence and machine learning in the analysis of digital health medical device data to detect early signals, trends, and other critical information.
- Draft decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, and reliability concerns.
- Forge mutually beneficial formal partnerships with medical device manufacturers, foreign agencies, professional scientific organizations, health care community, patient advocacy groups, academia, and other federal, state, and local stakeholders.
- Creates and sustains a strong and dynamic culture within the Division including organizational agility, a focus on continuous improvement, and 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 regulatory policy and guidance to share expertise and advise leadership on highly complex and precedent setting public health matters.
- Leads the strategic achievement of organizational goals, evaluating organizational performance and taking action 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, for a variety of audiences.

Desirable Education and Experience:
- Applicants with advanced degrees in engineering, biomedical engineering, physics, computer science, healthcare disciplines, or related field.
- 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, 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-DID-014"*** in the subject line. Applications will be accepted through **November 19, 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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