TITLE 21 VACANCY ANNOUNCEMENT

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)

Position: Director, Division of Imaging, Diagnostics & Software Reliability (DIDSR)

Series: The position of Supervisory Interdisciplinary Scientist may be filled by candidates from the following occupational series: Biologist (0401), Microbiologist (0403), General Engineer (0801), Materials Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858), Physical Scientist (1301), Physics Series (1310), Chemist (1320).

Location(s): Silver Spring, Maryland

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

Application Period: Friday August 21, 2020 through Monday September 21, 2020

Salary: Salary is commensurate with education and 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 Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

The mission of CDRH is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States. The Office of Science and Engineering Laboratories (OSEL) supports the CDRH mission of protecting and promoting public health. We undertake the highest quality science to provide our customers with the best methods, tools and expertise to ensure readiness for emerging and innovative medical technologies; develop appropriate evaluation strategies and testing standards; create accessible and understandable public health information; and deliver timely and accurate decisions for products across their life cycle.

The Division of Imaging, Diagnostics & Software Reliability (DIDSR) undertakes regulatory research programs related to the core business of CDRH in the area of

medical imaging systems and software tools including 3D breast imaging systems and CT devices; digital pathology systems; medical display devices including AR/VR; AI/ML and computer-aided diagnostics; biomarkers (measures of disease state, risk, prognosis, etc. from images as well as other assays and array technologies), and assessment strategies for imaging and other high-dimensional data sets from medical devices. DIDSR is also responsible for high-performance scientific computing administration and management for CDRH.

The Division of Imaging, Diagnostics & Software Reliability:

- Ensures readiness for emerging and innovative medical imaging and diagnostics technologies
- Contributes scientific expertise to regulatory reviews and new policy development
- Develops state-of-the-art methods for the design of clinical trials involving imaging devices and the evaluation of resulting trial data to enable more efficient and effective utilization of imaging data and more powerful clinical studies.
- Develops reliable and standardized test methods, data sets, and computational models to advance efficient regulatory pathways.

Position Summary:
As the Director of DIDSR, the selected candidate will be relied on to provide strategic guidance and oversight for all Division activities, technical, administrative, and budgetary, in support of medical device innovation, safety, and effectiveness. Additionally, the Director will serve as an expert liaison between the Center and the medical device manufacturing industry, as well as the scientific, standards, and healthcare communities and be charged with accelerating the innovation of new medical devices through contributions to translational medicine. If you are looking for an exciting new leadership opportunity that will allow you to directly enhance the lives of patients and their families, we encourage you to apply.

Supervisory Responsibilities:
The Division Director leads, manages, and sets strategy for DIDSR staff and serves as the technical authority and principal advisor to the OSEL Director on scientific and technical topics within DIDSR. The incumbent ensures DIDSR activities are aligned to the goals and priorities of OSEL. Provides technical, policy and administrative leadership and direction to the subordinate staff of the division through subordinate supervisors and exercises the full range of first and second-level supervisory responsibilities.

Exercises significant responsibilities in dealing with officials of other units or organizations, or in advising management officials of higher rank.

With the Office Director, the incumbent has responsibility for the development, establishment, and clearance of goals, objectives, and strategic plans for the Division; manages the overall work of the Division to enable achievement of the goals and objectives; oversees the revision of long range plans, goals and objectives of the Division; manages the development of program and policy changes in response to the

needs of the FDA-CDRH and revisions to Federal and Departmental laws, regulations, and requirements; manages organizational changes within the Division, including proposals to achieve maximum effectiveness and efficiency; and develops the Division's annual budget request.

Duties/Responsibilities:
The Director of DIDSR will:

- Ensure all Division activities, goals, and objectives align with Office and Center strategic priorities
- Effectively contribute to the advancement of the mission, vision, and values of the Office and Center
- Represent the Center, Office, or Division at internal and external meetings
- Cultivate relationships, internally and externally, to support the mission of DIDSR and OSEL
- Effectively communicate complex scientific concepts to diverse audiences to include, patients, healthcare providers, FDA leadership, medical device manufacturers, scientists, and policy makers
- Contributes scientific expertise to regulatory reviews and new policy development
- Lead the Division continuous quality improvement efforts
- Provide professional development opportunities for all Division staff, as well as serve as a mentor for less experienced staff.

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.

Professional Experience/Key Requirements:
To qualify for this position, successful candidates will be an accomplished, dynamic, and visionary senior executive scientist. The candidate should have significant experience and expertise in medical device design, research, and development, reliability testing and data interpretation, and leading multi-disciplinary scientists, clinicians, and other professionals in large-scale science-based organizations. Additionally, the right scientific executive will have a proven track record of leading people, galvanizing teams, and developing positive relationships with both internal and external stakeholders.

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

Desirable Education:
Applicants with a M.D., D.O., Ph.D., or an equivalent advanced degree in science, or engineering fields are highly desired.

Conditions of Employment:
- One-year probationary period may be required.
- Background and/or Security investigation required.
- U.S. citizenship is required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply:
Prior to applying, please see the following instructions:
- Documents to submit: electronic resume or curriculum vitae, cover letter containing a brief summary of scientific accomplishments, and copy of transcripts
- Compile all applicant documents into **one combined document (i.e. Adobe PDF)**
- Include Job Reference code ***"CDRH-OSEL-2020-LKI-02"*** in the email subject line.

- Email comprehensive applicant package/document OSELRecruitment@fda.hhs.gov by **Monday September 21, 2020**.

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