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 Strategic Partnerships and Technology Innovation (OST)

Open to current federal employees HHS-Wide.

Position: Deputy Office Director (Supervisory Interdisciplinary Scientist/Engineer)

Series: This position is interdisciplinary in nature may be filled by candidates from the following occupational series: Physician (0602), General Health and Science (0601), Biologist (0401), Microbiologist (0403), Consumer Safety Officer (0696), Physical Scientist (1301), Chemist (1320), Computer Scientist (1550), General Engineer (0801), Biomedical Engineer (0858), Electrical Engineer (0850), Materials Engineer (0806), Mechanical Engineer (0830), Dentist (0680), Regulatory Counsel (0301), Data Scientist (0301).

Location(s): Silver Spring, Maryland

Travel Requirements: This position requires up to 25% travel.

Application Period: Tuesday October 20, 2020 through Tuesday November 3, 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. OST is responsible for the Center's portfolio of: All Hazards Readiness & Response, Device Supply Chain Resilience, Patient Science & Engagement, Pediatrics & Special Populations, Health of Women, Standards and Conformity Assessment, Science and Strategic Partnerships, Digital Health, Medical Device Cybersecurity, Technology and Data Services, and

Innovation programs. These programs include national and international activities that cultivate the development of medical devices for unmet public health needs, improve patient access to medical devices, lead a coordinated and multi-pronged response to public health emergencies involving medical devices, including critical shortages, and address the scientific and regulatory challenges of bringing novel devices and disruptive technologies to market. OST accomplishes this by:

- Providing leadership in advancing partnerships with patient organizations, healthcare professional organizations, industry, scientific and other external organizations to support broad national and international patient-focused and regulatory science programs and activities related to the safety, effectiveness, and quality of medical devices and the safety of radiation-emitting products.
- Leading and facilitating collaboration in fostering the development of medical devices to respond to unmet public health needs and to address challenges of bringing innovative medical devices to market that are safe, effective and high quality.
- Providing leadership and strategic direction on software and digital health topics for the Center.
- Providing leadership, oversight, and coordination for the Center in matters relating to emergency preparedness and response activities involving Center for Devices and Radiological Health (CDRH)-regulated products or facilities.
- Providing world-wide leadership in standards implementation and utilization for medical device innovation and manufacturing, and radiation-emitting product safety.
- Directing and overseeing all aspects of the Center's data, informatics, and information technology programs to ensure effective design, development, and utilization of information systems, electronic data and analytic tools to optimize regulatory business processes.

Position Summary:
As Deputy Office Director for the OST the incumbent provides leadership and direction to a multidisciplinary workforce engaged in the execution of nationwide programs and the daily management of the Center’s partnerships and technology innovation activities and provides coordinative leadership to key officials and program managers in fostering greater engagement and collaboration between CDRH and external parties and advancing medical device innovation. The Deputy partners with the Office Director in the collaboration with national and international entities to drive innovation, standards and conformity assessment, patient science and engagement, health of women, and pediatrics and special populations.

Duties/Responsibilities:
Duties may include but are not limited to:

- As Deputy, the incumbent provides leadership in the development, implementation, execution, management and direction of the Office's broad national and international partnership and technology innovation programs and activities related to the safety, effectiveness and quality of all medical devices and the safety of radiation-emitting products.

- Provides leadership in advancing partnerships with patient organizations, healthcare professional organizations, industry, scientific and other external organizations to support broad national and international patient-focused and regulatory science programs and activities related to the safety, effectiveness, and quality of medical devices and the safety of radiation-emitting products.
- Facilitates collaboration in fostering the development of medical devices to respond to unmet public health needs and to address challenges of bringing innovative medical devices to market that are safe, effective and high quality.
- Provides leadership and strategic direction on software and digital health topics, emergency preparedness and response for the Center.
- Provides leadership, oversight, and coordination for the Center in matters relating to emergency preparedness and response activities involving CDRH-regulated products or facilities.
- Provides leadership in standards implementation and utilization for medical device innovation and manufacturing, and radiation-emitting product safety.
- Directs and oversees all aspects of the Center's data, informatics, and information technology programs to ensure effective design, development, and utilization of information systems, electronic data and analytic tools to optimize regulatory business processes.
- Represents and speaks for the OST Office Director in discussions, meetings, and conferences with top level agency officials, national/international industry representatives and scientific and academic organizations and groups, foreign officials, Members of Congress and/or their representatives, personnel from other executive departments and independent Federal agencies, State and local governmental counter parts and others.
- As designated, serves as the Acting Office Director for the OST.

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, you must possess technical experience and expertise including:

- Senior level management experience, which demonstrates strong leadership abilities;
- Expertise and knowledge regarding the development, evaluation, and commercialization of medical devices and challenges in bringing medical devices to market in the U.S.;
- Expertise in engaging and collaborating with external communities;
- Core innovation and problem-solving skills;
- Ability to articulate concepts clearly and in a compelling way and with solid design skills to support it; and
- Background in medicine, science, or administration of healthcare.

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 an advanced degree in science, engineering, or medical fields are highly desired.

Conditions of Employment:

- One-year supervisory 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:

Submit electronic resume or curriculum vitae, letter of interest, SF-50, and a copy of unofficial transcripts to CDRHRecruitment@fda.hhs.gov with ***"OST Deputy Office Director"*** in the subject line. Applications will be accepted through **November 3, 2020**.

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

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