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 Product Evaluation and Quality (OPEQ)
Office of Health Technology 3 (OHT3)

Open to U.S. Citizens.

Position: 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), Biologist (0401), Microbiologist (0403), General Health Scientist/Epidemiologist (0601), Nurse Consultant (0610), Consumer Safety Officer (0696), Physical Scientist (1301), Physicist (1310), Chemist (1320), General Engineer (0801), Material Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858), Mathematical Statistician (1529), and Statistician (1530).

Location(s): Silver Spring, Maryland

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

Application Period: Monday November 30, 2020 through Tuesday December 29, 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 Center for Devices and Radiological Health (CDRH) 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 Product Evaluation and Quality (OPEQ) is responsible for setting strategy and overseeing the Offices of Health Technology 1-7, Office of Clinical Evidence & Analysis (OCEA), Office of Regulatory Programs (ORP). Using a focused Total Product Lifecycle approach, the Office ensures quality end-to-end device evaluation, and the consistent interpretation and application of regulatory policy and guidance. The Office ensures that these activities are aligned to the overall strategy and priorities of CDRH and FDA and contains staff responsible for Clinical Affairs, Quality Management and Analysis, and Strategic Initiatives.

The Office of Health Technology 3 within CDRH's Office of Product Evaluation and Quality (OPEQ) is responsible for the total lifecycle (TPLC) review of reproductive, gastro-renal, urological and general hospital devices. The Office is also responsible for the CDRH Human Factors program.

Position Summary:
Reporting directly to the OPEQ Director, the Office Director partners in providing technical leadership and exercises exceptional scientific and engineering judgment in regulating various medical products. Judgment and technical skills are applied across the total product lifecycle including premarket, compliance/enforcement, device quality, and post market safety issues including the evaluation of complex issues involving sophisticated devices and highly controversial issues.

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

- Serves as the technical authority and principal advisor to the OPEQ Director on the total product lifecycle of devices including premarket evaluation, compliance and quality, and surveillance programs.
- Engages regularly with internal stakeholders and external stakeholders such as the medical device industry, trade associations, other Federal agencies, other countries, State agencies, and the general public.
- Oversees medical device reviews and the decision-making process on classifications, petitions, 510(k)s, HDEs, PMAs, PDPs, De Novos, 513(g)s, IDEs, and all supplements and amendments to these submissions. Signs off on complex medical and healthcare device reviews to ensure compliance with relevant standards and regulations.
- Provides technical and non-technical leadership to device advisory panels and panel members and consultants and provides guidance on classification actions, petitions, 510(k)s, PMAs, PDPs, De Novos, 513(g)s and IDEs with Center and Agency components or other organizations, when appropriate.
- Oversees adverse event report review, postmarket study development, review and compliance, and signal detection and review. Provides oversight of establishment inspection review, allegation of regulatory misconduct review, recalls, and other compliance and enforcement activities.
- Oversees medical and healthcare compliance activities including inspection classification, recall classification, labeling review, import alerts, custom device

reports and surveillance activities including MDR review and analysis, 522 Studies, PAS studies.

- Manages the Office's administrative and regulatory activities, including administrative suspense and documentation management in accordance with applicable regulatory guidance for all medical devices within the OHT3.
- Oversees the development, review, and revision of new and amended regulations, when applicable.
- Directs the development and interpretation of policy guidance in response to specific requests from the medical device industries, trade associations, other Federal agencies, other countries, State agencies, and the general public.
- Directs impact analyses of proposed changes to Agency laws and regulations, which affect the functions, program segments, and activities of the Office.
- Decides on changes and additions to the functions, program segments, and activities of the Office necessary to implement new regulations and develops various scenarios for dealing with expansion or contraction of the Office functions.
- Sets strategic direction and manages overall office performance on regulatory review operations, programs, and activities.
- Develops and implements policies and plans that are sound and feasible in relation to Office, OPEQ and Center goals and federal budgetary and economic realities.
- Determines short and long-range program requirements including schedules, priorities, scope, funding, and staffing consistent with goals and objectives established by the OPEQ Director.
- Makes assessments, in coordination with the OPEQ Director and evaluation of operations/priorities, as to where program changes may be required to plan for long-range operations.
- Manages a multi-disciplinary program, providing leadership and management oversight to subordinate staff and division directors. Provides technical and administrative leadership and direction to the subordinate staff of the Office through subordinate supervisors and exercises the full range of first and second-level supervisory responsibilities.

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:

- Managing of a multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with food, drugs and/or devices;
- Developing and evaluating policy/guidance and determining appropriate approaches regarding the regulation of food, drugs, and/or devices; and
- Leading the strategic achievement of organizational goals, evaluating organizational performance and taking action to improve performance.

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:

- Prior clinical and/or regulatory experience with the FDA.
- Excellent leadership and communication skills.
- Ability to work collaboratively with a diverse cadre of customers and stakeholders.
- Ability to build and work effectively within teams.
- Experience making recommendations regarding the management of regulatory submissions.

- Ability to prioritize and make critical decisions.

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:

Prior to applying, please see the following instructions:

- Documents to submit: electronic resume or curriculum vitae, cover letter describing why you are uniquely qualified for this, and copy of transcripts
- Compile all applicant documents into **one combined document (i.e. Adobe PDF)**
- Include Job Reference code ***"OHT3 Office Director"*** in the email subject line.
- Email comprehensive applicant package/document to CDRHRecruitment@fda.hhs.gov by **Wednesday, December 29, 2020**

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

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