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 In Vitro Diagnostics and Radiological Health (OHT7)

Position: OHT7 Deputy Office Director (Patient Safety and Product Quality)

Series: The position may be filled by candidates from the following occupational series: Biologist (0401).

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

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

Application Period: Friday May 7, 2021 through Tuesday May 11, 2021

Salary: Salary is commensurate with education, experience and comparable market pay and starts at $163,962.

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. OPEQ assures patients have access to high quality, safe and effective products throughout the total product lifecycle by implementing program areas through which medical devices are evaluated or cleared for clinical investigations and marketing. OHT7 is responsible for the in vitro diagnostic, radiological health, and mammography quality standards programs.

We invite you to listen as a CDRH employee talks about his passion for the work he does, the Agency's pioneering regulatory science culture and opportunities for professional growth, and why he loves working at FDA by clicking here.

Position Summary:

Reporting directly to the Office Director, Deputy Office Director leads, manages, and sets strategy for OHT7 and serves as the technical authority and principal advisor to the Office Director on scientific and technical topics within OHT7. Serves as the Acting Director in the Office Director's absence. The incumbent ensures OHT7 activities are aligned to the goals and priorities of OPEQ. Ensures OHT7 advances the Center's mission and vision. Implements the Center and OPEQ's Strategic Priorities. Develops and implements policies and plans that are sound and feasible in relation to OPEQ and Center goals and federal budgetary and economic realities.

Supervisory Responsibilities:
The Deputy Office Director leads, manages, and sets strategy for OHT7 staff and serves as the technical authority and principal advisor to the OHT7 and OPEQ Directors on scientific and technical topics within OHT7. The incumbent ensures OHT7 activities are aligned to the goals and priorities of OPEQ. Provides technical, policy 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.

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 Office; manages the overall work of the Office to enable achievement of the goals and objectives; oversees the revision of long range plans, goals and objectives of the Office; 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 Office, including proposals to achieve maximum effectiveness and efficiency; and develops the Office's annual budget request.

Duties/Responsibilities:
The Deputy Office Director:

- Shares with the director the responsibilities of leading, managing, and setting strategy for OHT7 and serves as the technical authority and principal advisor to the Office Director on scientific and technical topics within OHT7.
- Serves as the Acting Director in the Office Director's absence. The incumbent ensures OHT7 activities are aligned to the goals and priorities of OPEQ.
- Directs the OHT7 program management operations for regulating safety and effectiveness of all general medical devices, marketed in and utilized throughout the United States.
- Provides technical and scientific leadership and guidance in review of policy and procedures associated with the regulated medical device industry in patient safety and product quality.
- Serves as the Office focal point and primary expert in patient safety and product quality, providing information and consulting with individuals, federal agencies, private medical device industry, universities, and/or foreign governments on

consumer safety and patient safety issues.

- Advises and informs the OHT7 Director and other key agency officials on activities resources and related considerations which may affect or impact the planning, development and administration of patient safety and product quality programs.
- Represents the Office, Center Director and FDA (when necessary), and participates as the Office's scientific and regulatory authority, on all matters related to regulated medical device industry in patient safety in conferences, meetings and discussions with top level government officials, regulated industry representatives, the medical scientific and academic Communities, national and international scientific and health related professional organizations, representatives from foreign governments, etc.

Professional Experience/Key Requirements:

To qualify for this position, you must possess technical experience including:

- Knowledge of organizational, operational, and programmatic concepts and practices applied by public, private, or nonprofit standard development and regulatory agencies and/or organizations engaged in public health or other health-related areas of manufacturing standards development;
- 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;
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders;
- Knowledge of the regulatory total product lifecycle (TPLC) review process including: implementation of premarket review programs (e.g., 510(k), PMA, HDE, DeNovo, IDE, etc.), compliance and quality programs (e.g., Establishment Inspection Report, Regulatory Audit Reports, Recalls, Allegations of Regulatory Misconduct, Labeling, Enforcement Actions, etc.), and surveillance programs (e.g., Medical Device Reports, Post Market Surveillance Studies, Safety Signals, etc.).

Desirable Education:

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

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:

- 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 ***"OHT7 Deputy Director"*** in the email subject line.
- Email comprehensive applicant package/document to CDRHRecruitment@fda.hhs.gov by **Tuesday May 11, 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.

The Department of Health and Human Services is an equal opportunity employer

with a smoke free environment.

FDA is an equal opportunity employer.