TITLE 21 VACANCY ANNOUNCEMENT

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF PRODUCT EVALUATION AND QUALITY (OPEQ)
OFFICE OF HEALTH TECHNOLOGY V (OHT5)
OFFICE OF NEUROLOGICAL AND PHYSICAL MEDICINE DEVICES (ONPMD)

Position: Associate Director for Policy, OPEQ/ONPMD

Series: This is an interdisciplinary position that may be filled in the following series: Physician (0602), Biologist (0401), Microbiologist (0403), General Health Scientist (0601), Consumer Safety Officer (0696), General Engineer (0801), Material Engineer (0806), Biomedical Engineer (0858).

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

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

Application Period: Tuesday June 15, 2021 through Thursday June 28, 2021

Salary: Starting at $144,128 and is set commensurate with qualifications.

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. OHT5 is responsible for the total lifecycle (TPLC) review of neurological and physical medicine devices.

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.

Duties/Responsibilities:

- Serves as the technical expert in policies and regulations that impact the activities of OHT5. Provides scientific and technical leadership and expertise in policies and procedures, with emphasis on testing and evaluation, and quality control procedures
- Provides evaluations to the OHT5 Director and other Senior CDRH managers to make sure that OHT5 stays focused on appropriate regulatory science implementation and in compliance with policy
- Interacts with multiple relevant device OHT5 file review groups and OHT5 teams as designated by the OHT5 Director. In this way the incumbent helps maintain consistent scientific and/or engineering and regulatory review policies that are consistent with the OHT5 regulatory science mission and MDUFA policies
- Formulates consistent scientific and/or engineering review processes through guidance and other mechanisms to ensure that OHT5 is promoting a consistent and transparent regulatory and scientific framework that is consistent with MDUFA and least burdensome policies
- Reviews and evaluates Office activities in terms of achieving program goals and objectives and accomplishing assigned functional responsibilities.

Professional Experience/Key Requirements:

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

- Developing and recommending approaches for complex situations using FDA policies, procedures and regulations (e.g. the Federal Food, Drug and Cosmetic Act); and
- Serving as a scientific reviewer, lead reviewer, expert, team lead, or analyst in a regulatory program associated with devices, drugs, or food; and
- Leading activities of a regulatory program, including experience with appeals and panels, advising on policy/guidance for FDA regulated products, and preparing transcriptions, letters and documentation related to these activities.

Desirable Qualifications/Experience:

- Skillful in effectively interpreting and presenting complex information and concepts, in both written and oral formats.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Ability to actively embrace diversity by actively promoting an inclusive workplace that maximizes the talents of each person.
- Ability to focus on objectives and results when considering the various alternatives to a decision.

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,
  - Standard Form 50 (SF-50)
  - Cover letter describing why you are uniquely qualified for this
  - Copy of transcripts
- Compile all applicant documents into **one combined document (i.e. Adobe PDF)**
- Include Job Reference code ***"2020-OHT5-IO-011"*** in the email subject line.
- Email comprehensive applicant package to CDRHRecruitment@fda.hhs.gov

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.