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 Clinical Evidence and Analysis (OCEA)
Division of Clinical Evidence and Analysis III (DCEA3)

Position(s): Assistant Director for Clinical Evidence Outcomes Research 2, OPEQ/OCEA/DCEA3

Series: The position of Assistant Director may be filled by candidates from the following occupational 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): Remote Eligible

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

Application Period: March 23, 2023, to April 20, 2023

Salary: Salary is commensurate with education and experience and starts at $132,368.00

Conditions of Employment: U.S. 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. OCEA is responsible for the development of policy related to CDRH's oversight and regulation of clinical trials and other sources of clinical evidence for medical devices. This includes development and implementation of policies

related to human subject protection, good clinical practice, and appropriate collection of real-world evidence (RWE).

Position Summary: Reporting directly to the OCEA/DCEA3 Division Director, you will serve as the technical expert in policies and regulations that impact the activities of OCEA and provide scientific and technical leadership and expertise in policies and procedures, with emphasis on testing and evaluation, and quality control procedures.

Duties/Responsibilities: The Assistant Director also performs the following duties:

- Serves as the technical expert in policies and regulations that impact the activities of OCEA. 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 Division Director and other Senior CDRH managers to make sure that DCEA3 stays focused on appropriate regulatory science implementation and in compliance with policy
- Interacts with multiple relevant device file review groups and teams as designated by the Director. In this way the incumbent helps maintain consistent scientific and/or engineering and regulatory review policies that are consistent with the regulatory science mission and MDUFA policies
- Formulates consistent scientific and/or engineering review processes through guidance and other mechanisms to ensure that DCEA3 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 demonstrate in your resume the necessary qualifying experience for this position, which includes the following:

- Knowledge of analytical theories and statistical principles including mastery of techniques for premarket and post-market evaluation/surveillance of medical devices.
- Experience in evaluating, developing, and re-engineering clinical studies, as well as developing, applying, and validating statistical tools, endpoints, and methodologies.
- Ability to understand and interpret statistical methods and information and communicate the statistical interpretations to both scientific and lay audiences, in written and presentation formats
- Strong skills in using statistical tools and program languages, as well as proficiency in collating
- and analyzing epidemiologic data.

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

Candidates must possess the required individual occupational requirements to qualify for the series. Please use the following link to review the requirements: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/1500/mathematical-statistics-series-1529/.

Physician, GP-0602: Must be a U.S. citizen with Doctor of Medicine (M.D.), Doctor of Osteopathic Medicine (D.O.) or equivalent from a school in the United States or Canada. The degree must have been approved by a recognized accrediting body at the time the degree was obtained.

A Doctor of Medicine or equivalent degree from a foreign medical school that provided education and medical knowledge substantially equivalent to accredited schools in the United States may be demonstrated by the Educational Commission for Foreign Medical Graduates, or a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country. Candidates for Civil Service or U.S. Commissioned Corps must possess a valid license to practice medicine in any state in the U.S. It is highly desired that the prospective candidate has eligible Board Certification.

Licensure: Applicant must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

How to Apply: Prior to applying, please see the following instructions:

- Documents to submit: An electronic resume or curriculum vitae, cover letter describing why you are uniquely qualified for this, and copy of unofficial transcripts
- Compile all applicant documents into **one combined document (i.e., Adobe PDF)**
- Include Job Reference code ***OCEA-DCEA3 Assistant Director 2023*** in the subject line. Email comprehensive applicant package/document to CDRHRecruitment@fda.hhs.gov by **April 20, 2023.**

Conditions of Employment:

- One-year probationary period and one-year supervisory probationary period may be required.
- Background and/or Security investigation required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption.

Additional Information:

- Due to COVID-19, the agency is currently in an expanded telework posture. If selected, you may be expected to temporarily telework, even if your home is located outside the local commuting area. Once employees are permitted to return to the office, you will be expected to report to the duty station listed on this announcement within 45 days. At that time, you may be eligible to request to continue to telework one or more days a pay period depending upon the terms of the agency's telework policy. As required by Executive Order 14043, Federal executive branch employees are required to be fully vaccinated against COVID-19 regardless of the employee's duty location or work arrangement (e.g., telework, remote work, etc.), subject to such exceptions as required by law. If selected, you will be required to be vaccinated against COVID-19 and will

receive instructions on how to provide documentation.

- This is a non-bargaining unit position.
- PHS Commissioned Corps Officers interested in performing the duties of this position within the Commissioned Corps may apply to this announcement. Officers must follow the instructions for how to apply and include their most recent orders in addition to the required documents. If selected, candidates will be referred to (CC) personnel and not as candidates for a Cures appointment.
- This is a confidential filing position, subject to FDA's prohibited financial interest regulation and may require the incumbent of this position to divest of certain financial interests. If selected, the employee must complete ethics requirements and file an annual financial disclosure report (OGE-450 form). 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.
- 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. 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 / FDA is an equal opportunity employer with a smoke free environment.