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 III (OHT3)

Position: Physician (Chief Medical Officer)

Series: The position may be filled by candidates from the following occupational series: Physician 0602

Area of Consideration: Open to the Public

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

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

Application Period: October 19, 2022 – November 18, 2022

Salary: Salary is commensurate with education and experience and starts at $195,000.

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 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. OHT3 is responsible for the total lifecycle (TPLC) review of reproductive, gastrointestinal, transplant, renal, obesity, urological, and general hospital devices. The office is also responsible for the CDRH Human Factors program.

Position Summary: Reporting directly to the Office of Health Technology 3 (OHT3) Office Director, you will serve as program manager and primary contact for medical device clinical issues. You will serve as a Chief Medical Officer advisor to the Office Director, Super Office Director, and other OPEQ and CDRH leadership. Also, the incumbent provides senior advice and leadership to a scientific, clinical, professional, and technical staff throughout the Office. The Chief Medical Officer is a nationally and internationally recognized clinician with a specialty emphasis on clinical trial design and evaluation, and quality control procedures.

Duties/Responsibilities: The Chief Physician also performs the following duties:

- Serves as the clinical authority in reviewing and evaluating clinical and research findings, scientific properties, analyses, laboratory and clinical behavior, and the impact of these factors and properties on the safety and effectiveness of medical devices.
- Provides an authoritative analysis of scientific data submitted to the Agency; and to develop new and innovative approaches to scientific testing as required for medical device reviews by FDA.
- Leads in the planning and development of the Office's clinical policy initiatives and makes

decisions and/or recommendations that have major impacts on the Office's clinical activities in its broad mission of protecting the Nation's public health.
- Serves as the Office's primary contact for medical device clinical issues. Provides expert and authoritative advice, guidance, assistance, interpretations, consultations and recommendations to top level and senior Agency and Departmental officials, program directors, scientific and professional personnel, industry representatives, intra/inter-governmental counterparts and others concerning medical device policies, programs and activities.

Professional Experience/Key Requirements: To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which is equivalent to the following:

- Clinical and medical expertise related to clinical trial conduct, protection of human subjects, registry infrastructure development, and execution of safety studies.
- Advising, training, and guiding a multi-disciplinary staff responsible for medical, clinical, public health and/or regulatory activities associated with medical products (i.e., devices, biologicals, drugs, etc.).
- Expert in interpreting and presenting complex scientific, medical, clinical, and regulatory information and concepts, in both written and oral formats for a variety of audiences.
- Clinical and medical expertise on medical devices; professional knowledge and understanding of current FDA regulations, policies, and procedures pertaining to safe and effective medical devices.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.

Desirable Qualifications/Experience:

- Excellent oral and written communication skills.
- Ability to work collaboratively with a diverse cadre of customers and stakeholders.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.

Basic Qualifications: Physician, (GP-0602): A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates, a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

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. It is highly desired that the prospective candidate has eligible Board Certification.

Additional Conditions of Employment

- United States Citizenship is required.
- One-year 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.

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

1. Submit an electronic resume or curriculum vitae, copy of your active medical license, copy of your transcripts (unofficial).
2. Include Job Reference code ***"2020-OHT3-IO-017"*** in the email subject line.
3. Email applicant package to CDRHRecruitment@fda.hhs.gov.

Background Investigation/Security Clearance Requirements: If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Vaccination Requirements: To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

Ethics Clearance Requirements: This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information, please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity: 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: 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.

E-Verify: The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

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

FDA is an equal opportunity employer.