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 V (OHT5)
Division of Health Technology V A (DHT5A)

Application Period: Monday, November 6, 2023, through Monday, December 4, 2023

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Physician (Neurosurgeon, Neurologist, Physiatrist, or Psychiatrist)

Series: Physician 0602

Location(s): Remote Eligible

Work Schedule: Full-Time

Salary: Salary is commensurate with education and experience and starts at $165,000.00.

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% travel or less

Supervisory: No

Bargaining Unit: 8888

This position is being filled under a stream-lined 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 this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

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 are safe, and effective.

The mission of the Center for Devices and Radiological Health (CDRH or Center) 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. The Office of Product Evaluation and Quality (OPEQ or Super Office) 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. The Office of Health Technology V (OHT5 or Office) is responsible for the total product lifecycle (TPLC) review of neurological and physical medicine devices.

Meet one of the faces behind CDRH here.

Duties/Responsibilities

Reporting directly to the Assistant Director, the Physician will serve as a clinical authority and technical expert for the review of cutting-edge neurological and physical medicine devices. The incumbent will serve as a Physician advisor to the Office Director, Super Office Director, and other OPEQ Offices, and CDRH leadership. The incumbent provides advice and leadership to a scientific, clinical, professional, and technical staff throughout the Office. The Physician also performs the following duties:

- Serves as an authority on the latest developments in health care policy and the neurological and physical medicine medical device industry. As such, conducts regulatory policy reviews related to the development aspects of medical devices, diagnostic equipment, and products used in this medical device space.
- Provides oral and written consultations for various types of regulatory submissions across a wide range of neurological and physical medicine devices to include, but not limited to neurological surgery, acute stroke, movement disorders, Alzheimer's disease, psychiatric disorders, or physical medicine diseases/disorders.
- Utilizes clinical expertise and technical knowledge to serve as an authoritative voice and principal advisor to the DHT5A Assistant Director and the OHT5 Office Director on matters regarding neurological and physical medicine medical devices, diagnostic equipment, and products, encompassing the entire product lifecycle.
- Provides guidance to industry to ensure approaches to research studies follow FDA regulatory protocols, with a particular emphasis on clinical testing and evaluation, for novel and predicate neurological and physical medical devices and products.
- Evaluates proposed clinical trial protocol(s) for their ability to assess the safety, effectiveness, and reliability of new neurological and physical medicine medical devices under development.
- Provides authoritative analysis of the scientific data submitted in neurological and physical medicine device regulatory submissions and assists in the interpretation of post-market adverse event data.
- Provides expert and authoritative advice, guidance, assistance, interpretations, consultations and recommendations to senior Agency and Departmental officials, program directors, scientific and professional personnel, industry, representatives, and intra/inter-governmental counterparts.
- Offers evidence-based recommendations regarding classification and petitions for the reclassification of new neurological and physical medicine medical devices, as well as

identifies areas where standards need to be developed.
- Leads the planning and development of clinical policy initiatives and makes recommendations that have major impacts to the Agency's broad mission of protecting and promoting the Nation's public health.
- Supports review staff by sharing clinical expertise in the pre-market, compliance, and post-market surveillance spaces, as well as regulatory policy knowledge and interpretation

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates

    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement: Although this position does not involve direct patient care duties, candidates must possess the required occupational requirements to qualify. A degree from an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *Degree from Foreign Medical School: 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.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada. Please use the following link to determine the series qualifications: Physician (0602)

Professional Experience: 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 experience in neurological surgery (including functional neurosurgery), acute stroke, movement disorders, Alzheimer's disease, psychiatry, or physical medicine and rehabilitation and knowledge of the science behind clinical decisions related to these clinical procedures, conditions, and diseases.
- Experience in advising, training, and guiding multi-disciplinary staff in a clinical, public health or regulatory environment.
- Expertise in interpreting and presenting complex scientific, medical, clinical, or 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 wide range of customers and stakeholders.
- Possession of a Doctor of Medicine from a school in the United States, its Territories, the District of Columbia, or Canada approved by a recognized accrediting body in the year of the applicant's graduation.

Desired Professional Experience: The ideal candidate will possess:

- Excellent leadership and communication skills.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.
- Ability to design and critically review clinical trials.
- Diplomates of the American Board of Psychiatry, Neurology, Physical Medicine and Rehabilitation, or Neurological Surgery is a plus.

How to Apply

How to Apply: Submit resume or curriculum vitae, transcripts with cover letter by **Monday, December 4, 2023** to CDRHRecruitment@fda.hhs.gov. Compile all applicant documents into one combined document (i.e., Adobe PDF). Candidate resumes may be shared with hiring official within the CDRH with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". Please include the following Job Reference ID in the subject line of your email submission: ***OHT5 Physician – Last Name, First Name***

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.

Educational Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify

vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university.For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.
- 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.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: This position requires a **Public Trust/Moderate Risk** security clearance.

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

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

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.

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.

Announcement Contact

For questions regarding this Cures position, please contact CDRH-Title-21-Recruitment@fda.hhs.gov.

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

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