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 1 (OHT1)
Division of Health Technology 1C (DHT1C)

Application Period: April 1, 2024, through April 30, 2024

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 (Interventional Pulmonologist)

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: This position requires less than 10% of travel

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 Regulatory 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) 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 I (OHT1) is responsible for the development of policy related to CDRH's oversight and regulation of clinical trials and other sources of clinical evidence for ophthalmic, anesthesia, respiratory, ear, nose, and throat (ENT), and dental 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).

Duties/Responsibilities

The Physician (Interventional Radiologist) reports directly to the OHT1/DHT1C Division Director and will serve as the clinical and technical expert in the field of Pulmonary medicine, specifically Interventional Pulmonology. The Physician, Interventional Pulmonologist, provides clinical, scientific, and technical leadership and expertise in policies and procedures with an emphasis on testing, evaluation, and quality control standards regarding medical devices used in the diagnosis and treatment of conditions/ disorders of the lungs, airway, and pluera.

- Serves as an authority on the latest clinical advancements and developments in health care policy associated with the respiratory medical device industry. As such, she/he will conduct clincal data and regulatory policy reviews related to medical devices, diagnostic equipment, and products used in Interventional Pulmonology procedures.
- Utilizes clinical expertise and technical knowledge to serve as an authoritative voice and principal advisor to the DHT1C Assistant Director and the OHT1 Office Director on matters regarding respiratory medical devices, diagnostic equipment, and products, encompassing the entire product lifecycle.
- Offers evidence-based recommendations regarding classification and petitions for the reclassification of new respiratory medical devices, as well as identifies areas where standards need to be developed.
- Serves as a clinical authority on the latest developments in the health care policy and medical device industries of OHT1.
- Develops guidelines for the study and development of respiratory medical devices and pulmonary products classified in the premarket approval space.
- Provides guidance to industry to ensure approaches to research studies follow FDA regulatory protocols for novel and predicate respiratory medical devices and pulmonary products.
- Evaluates proposed clinical trial protocol(s) for their ability to assess the safety, effectiveness, and reliability of new respiratory medical devices and pulmonary products under development.
- Evaluates respiratory medical device and pulmonary product clinical trial findings, risk to benefit data, scientific properties, safety data, and the overall impact of existing devices, as well as new technologies submitted to the Center.
- 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.

- Reviews and assesses the safety implications from post-market surveillance data and adverse event reports and recommends appropriate regulatory courses of actions.
- Coordinates, conducts, and issues post market surveillance determinations (e.g., Medical Device Reports, Post Market Surveillance Studies, Safety Signals, etc.)
- Coordinates, conducts, and issues post-market compliance and quality determinations (e.g., Establishment Inspection Report, Regulatory Audit Reports, Recalls, Allegations of Regulatory Misconduct, Labeling, Enforcement Actions, etc.)

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:
Candidates must possess the required occupational requirements to qualify. Please use the following link to determine the series qualifications: Physician, 0602

Desired Education Requirement:
Our ideal candidate will have completed an Interventional Pulmology Fellowship.

Professional Experience:
Our ideal candidate will possess:
- Ability to collaborate with multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with medical products (i.e., devices, biologicals, drugs, etc.).
- Skill in identifying challenges, gathering information, drawing conclusions, and recommending solutions to complex issues.
- Ability to interpret and assess scientific data and technical reports to determine the safety and effectiveness of medical products.
- Ability to provide scientific support for regulatory questions and decisions regarding specific requests from medical device and health technology industries and other Federal agencies.

Desired Professional 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.

How to Apply

Submit resume or curriculum vitae (CV) **and** cover letter by **April 30, 2024** to CDRHRecruitment@fda.hhs.gov. Please adhere to the following submission protocol:

1. **Cover letter and resume or CV should be one combined PDF document.**
2. **Please reference DHT1C-OHT1 Physician March 2024, in the subject line of your email submission.**

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".

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.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive with a Risk Level of **Moderate**

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 the 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.

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 CDRHRecruitment@fda.hhs.gov

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

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