Title 21 Vacancy Announcement Physician
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Medical Policy (OMP)
Office of Medical Policy Initiatives (OMPI)
Division of Clinical Trial Quality (DCTQ)

Application Period: July 17, 2024 – July 31, 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

Series: AD- 0602

Location(s): Silver Spring, MD

Salary: Starting at $165,000-$262,150

Work Schedule: Full-Time

Cures Band(s): Table 3, Band C

Full Performance Band Level: Band C

Travel Requirements: Up to 25%

Bargaining Unit: 3591

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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 safe, and effective.

The mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential

public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

The Office of Medical Policy (OMP) is responsible for directing medical policy programs and strategic initiatives, contributing leadership and scientific advice in clinical trial and non-interventional study design, and providing consultation and direction in policy issues related to real-world evidence, human subject protection, and good clinical practice. OMP is also responsible for developing regulations, guidance documents, and procedures related to medical policy issues, as well as for regulation of patient labeling and prescription drug promotion and advertising. OMP responsibilities specifically include the evaluation of real-world evidence with a focus on effectiveness, comparative effectiveness, and comparative safety.

The Office of Medical Policy Initiatives (OMPI) mission includes providing oversight and direction for the development of medical policies and procedures pertaining to drug development, drug approval, bioresearch monitoring, human subject protection, post market surveillance processes, and to collaboratively enhance professional and patient labeling.

The Division of Clinical Trial Quality (DCTQ) within the Office of Medical Policy Initiatives (OMPI), provides oversight and direction for development of medical policies and procedures pertaining to clinical trial quality.

Duties/Responsibilities

As a **Physician**, the incumbent provides clinical, medical, scientific, regulatory, and advisory services to the Director of DCTQ and other leadership within OMPI, OMP, and CDER on matters involved in planning, and conducting policy development and implementation related to all medical product reviews, which are essential to making sure that safe and effective drugs are available to improve the health of the people in the United States.

- Serves as a medical consultant and scientific advisor to professional and technical staff and provides medical and scientific expertise for the development of regulations, guidance, and other policy documents.
- Consults on drug development and drug approval processes, study designs including randomized controlled trials, and clinical trial/investigation quality related issues including bioresearch monitoring and human subject protection.
- Reviews proposals for statutes, regulations, guidance's, and policies across a wide range of complex and/or emerging subject matter areas; develops and/or implements legislation.
- Develops policy solutions that involve the application of advanced medical, clinical, and regulatory expertise across the range of topics. Develops solutions to problems through knowledge of experimental designs, theories and practices utilized in drug development and clinical trial quality.
- Actively participates in internal and external engagements, including as a presenter,

associated with policies that are related to FDA's regulation and clinical review of medical products. Represents the division on committees and meetings concerning novel and/or innovative regulatory approaches, human subject protections requirements and regulations as well as other regulations and guidance's across the lifecycle of drug development.

- Provides guidance, knowledge management, mentoring, and/or training to professionals within FDA on matters regarding national and international regulations surrounding human subject protections requirements and other regulations and guidance across the lifecycle of drug development.
- Reviews current agency policy and regulations and assists with the preparation of recommendations to leadership for changes.

Supervisory Responsibilities: N/A

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.
- One-year probationary period may be required.
- 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.

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:
Physician, AD-0602 Series:

A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent.

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 United States or Canada.

Desired Education: Our ideal candidate will possess one or more advanced degrees in public health, epidemiology, medical science, quantitative science, and/or related fields.

Desired Professional Experience:
Our ideal candidate will possess:

- Experience in review of medical products, statutes, regulations, guidance's, and precedents, which relate to the activities of government organizations.
- Experience in applying knowledge of scientific methods and agency policies related to clinical safety and effectiveness assessments in medical product development.
- Experience with bioresearch monitoring, human subject protection, and other clinical trial quality issues.
- Ability to resolve unique or novel, complex, and challenging problems in the context of regulatory review of medical products.
- Ability to communicate orally and in writing, and to gather and convey information and make oral presentations.
- Ability to apply principles of epidemiology and complex epidemiologic methods.
- Ability to collaborate with internal and external interested parties.

Education 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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/Moderate Risk

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.

How to Apply

Submit resume or curriculum vitae with cover letter by **July 31, 2024,** to: CDER-OMPI-Jobs@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference Job Reference ID: **T-12-2024-DCTQ** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact CDER-OMPI-Jobs@fda.hhs.gov.

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