Title 21 Vacancy Announcement
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 Medical Policy Development (DMPD)

Application Period: August 12, 2024 – August 26, 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: Health Scientist Policy Analyst

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $139,395

Work Schedule: Full-Time (Telework Eligible)

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

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) 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 nonprescription 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, including evaluation of real-world evidence with a focus on effectiveness, comparative effectiveness, and comparative safety use cases as mandated by 21st Century Cures Act. OMP provides leadership and scientific advice in novel clinical trial designs, in particular the use of new technologies, and direction in policy issues related to human subject protection and good clinical practices.

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 Medical Policy Development (DMPD) mission includes coordinating and collaborating with relevant program areas to ensure optimal FDA scientific and technical input for ongoing policy initiatives in areas pertaining to human drug development, human drug approval, bioresearch monitoring, and human subject protection.

Duties/Responsibilities

As a **Health Scientist Policy Analyst**, the incumbent is responsible for:

- Develops and revises policy, program, regulation, and guidance documents involving complex and high priority matters that state or interpret Center or FDA policy for the regulated industry.
- Conducts regulatory and legal research to further medical policy programs on broad topics of national scope.
- Maintains current knowledge about legislations, regulations, guidance, internal policies and procedures, and trends in the pharmaceutical and health care industries, in areas such as clinical trial modernization, clinical trial diversity, and professional and patient labeling, and informs Division and Office management and staff of new information that is important from a regulatory or scientific perspective.
- Provides policy subject matter expertise while collaborating with Division/Office staff and management to strengthen the regulatory, scientific, and technical aspects of programs and actions. Ensures alignment with management goals and 3dvocates for the

Division/Office.

- Provides health science and technical expertise and leadership for cross-discipline working groups engaging both internal and external stakeholders and assumes primary drafting responsibility for the group work products, including synthesizing input from multiple sources to achieve comprehensive, and coherent policy.
- Provides expert advice and recommendations to other CDER and FDA offices on the development and implementation of health science policies and issues, including new or updated regulations, guidance, and policy documents through formal and informal collaborative channels.
- Drafts and delivers presentations to Center and Agency leadership and at external conferences and professional meetings on current policy developments at the agency and serves as a means of eliciting the concerns and criticisms of the regulated industry. On occasion serves as the sole representative of FDA during these meetings.
- Consults with staff at all levels of the agency to identify areas of disagreement within the Center or between the Center and other units of FDA. The result of these consultations is to resolve disagreements through decision memoranda or meetings, articulating any policy consensus reached by senior officials, including the Commissioner in the process.
- Drafts, reviews, and summarizes responses to public comments received on proposed regulations, recommending adoption or rejection of counter-proposals contained in comments for Division and Office level approval.
- Prepares replies to correspondence from the regulated community and other interested persons on health science issues that are industry-wide in scope or have broad health implications and that concern precedent-setting interpretations of FDA policy.

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.

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:

General Medical and Healthcare, AD-0601 Series

For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Education: Our ideal candidate will possess an advanced degree in public health, or another related field is preferred.

Desired Professional Experience:
Our ideal candidate will possess:

- Minimum of 5 years of experience developing, revising, and implementing complex regulatory policy documents, including industry guidance, SOPs, and Federal Register notices.
- A bachelors, masters, professional, or doctoral degree in the health/life sciences, public health, or other related disciplines. Demonstrated ability to work independently, work on a team, and to develop networks, build alliances, and collaborate across boundaries to build strategic relationships and achieve common goals.

- Proven track record leading diverse working groups to develop cohesive policy positions and deliverables. Skilled at building consensus among team members with varying viewpoints.
- Demonstrated knowledge of drug policy development and policy analysis practices sufficient to analyze a wide range of complex, and highly technical policy issues.
- Demonstrated expertise in regulatory policy related to drug development, approval, labeling, and marketing. Familiarity with relevant legislation such as the FD&C Act, PHS Act, and 21 CFR regulations.
- Proven ability to think strategically and anticipate potential policy implications. Skilled at
- analyzing complex issues and providing evidence-based recommendations to leadership.
- Demonstrated ability to independently plan and conduct in-depth regulatory research and analysis to inform policy development and decision-making.
- Ability to effectively communicate orally and in writing and work with staff at all levels of the organization including those with varying levels of domain expertise.
- Excellent presentation skills with the ability to effectively communicate complex policy
  information to a range of audiences. Adept at planning and facilitating meetings with internal and external stakeholders.

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 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 qualifications 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 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 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 **August 26, 2024,** to: CDER-OMPI-Jobs@fda.hhs.gov. Candidate resumes may be shared with hiring officials 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-13-2024-DMPD** in the email subject line.

How I Will Be Evaluated

Candidates may be evaluated based on their cover letters and resume or curriculum vitae. Additionally, candidates may be evaluated on interview(s), review of requested work samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact Sabrina Smith, Administrative Officer at sabrina.smith@fda.hhs.gov.

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

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