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 Program (DMPP)

Application Period: August 15, 2024 – August 29, 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: Supervisory Health Scientist Policy Analyst

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $139,395

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 25%

Bargaining Unit: 8888

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, 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 Programs (DMPP) is responsible for coordinating and collaborating with relevant program areas to ensure optimal FDA scientific and technical input for ongoing policy initiatives, developing and managing new sciences and technology policy initiatives pertaining to the drug development, drug approval, and post market surveillance process.

Duties/Responsibilities

As a **Supervisory Health Scientist Policy Analyst, the incumbent** handles highly complex and difficult assignments of national scope and significance, requiring judgment and recommendations resulting in precedents for subsequent regulatory actions or industry practices. The incumbent also works in collaboration with the Division Director.

- Leads the Division's policy analysis, development, and implementation efforts related to FDA's enabling legislation, regulations, and general policies impacting the Division’s policies and projects. Ensures regulations and policies developed within the Division's purview are consistent with applicable statutory requirements under FDA's enabling legislation, as well as existing policies, guidance documents, and industry practices. Critically evaluates the need and justification for Division’s proposed projects and policies prior to implementation.
- Identifies and resolves a broad range of key and complex policy issues pertaining to the Division’s projects and programs concerning application of FDA’s enabling legislation, pertinent guidance, and regulation, and/or general legislation.
- Provides health science/technical leadership for cross-disciplinary workgroups and synthesizes input to develop comprehensive policy work products. This includes leading intra-agency teams comprised of scientists, clinicians, regulatory experts, legal counsel, and other subject matter experts from across FDA's medical product centers on overarching initiatives that cut across disciplines like combination products, digital

health technologies, or novel clinical trial designs. Represents the Division as the authoritative expert in meetings with internal and external stakeholders, including industry, other government agencies, professional organizations, academia, and the public.

- Identifies resource needs and priorities to achieve the Division's operational plans and strategic objectives. Plans, organizes, and anticipates resource needs for concurrent policy activities.
- Collaborates with internal interested parties across FDA and CDER, including participating in intra-agency workgroups (e.g., includes CDRH or CBER representatives), to ensure consistency in policy implementation and application of regulations.
- Conducts in-depth analysis and provides technical advice based on comprehensive reviews and evaluations of pertinent regulations, initiatives, and policies. Provides recommendations to Division management and others when requested (e.g., Center Director, Commissioner) to enhance the scope, coverage, content, and overall effectiveness of these programs in achieving Division and Office goals and outcomes. Conducts special studies and investigations on specific program issues as needed. Drafts policy statements, regulations, legislation language and other technical documents.
- Collaborates with Division leadership, identifies key issues such as gaps in existing policies, barriers to efficient review processes, or emerging areas requiring new policy frameworks. Resolves complex regulatory problems and implements actions such as drafting new guidance, modifying review procedures, or developing comprehensive policy strategies to address identified issues.
- Identifies emerging regulatory needs, intricate policy dilemmas, or areas requiring new precedents. Drives assessment and analysis efforts, then initiates implementation of substantive policy actions, rules, guidance documents or procedures.

Supervisory Responsibilities: Provides direction, oversight, and leadership to subordinate team leaders, regulatory counsels, project managers, and policy analysts. Provides occupational-specific technical and administrative direction and supervision at least 25 percent of the time to subordinate staff performing the work and functions of the organization. Plans work to be accomplished by subordinates, sets, and adjusts short-term priorities, and prepares schedules for completion of work. Assigns work to subordinates based on priorities, selective consideration of the difficulty and requirements of assignments, and the capabilities of employees. Evaluates work performance of subordinates. Manages programs and projects through both traditional hierarchy and matrix design and ensures work assignments are carried out. Ensures the Division's goals, objectives, work plans, and products align with the organization's strategic plan, mission, vision, and values. Helps to identify, establish, and work towards strategic objectives and goals for the Division. Obtains resources needed to achieve the Division's mission.

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 supervisory 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:

General Medical and Healthcare, AD-0601 Series
Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the US Department of Education at the time the degree was obtained.

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

Desired Education: Our ideal candidate will possess a masters or doctoral degree in the health/life sciences, public health, and other related disciplines. A master's or doctoral degree in a field related to health sciences, public health, regulatory affairs, health policy, or other disciplines directly relevant to health system administration.

Desired Professional Experience:
Our ideal candidate will possess:

- Extensive experience (7+ years) developing, analyzing, and implementing policies and procedures related to the regulation of medical products such as drugs, biologics, devices, etc.
- Deep knowledge of FDA's regulatory authorities, practices, and statutory requirements.
- In-depth understanding of the drug development process, including clinical research, regulatory review, and post-market surveillance.
- Significant experience (5+ years) leading or overseeing teams or groups responsible for health policy, regulatory compliance, or public health program implementation.
- Demonstrated skills in strategic planning, project management, and evaluating impact of policies/initiatives.
- Proven ability to build collaborative relationships and networks across organizational boundaries. Experience achieving alignment and shared goals through effective negotiation and communication with diverse stakeholders.
- Excellent oral and written communication skills with the ability to clearly convey complex regulatory concepts and policy rationale to technical and non-technical audiences at all levels.
- Experience synthesizing inputs from cross-functional teams and subject matter experts to develop comprehensive, cohesive policy frameworks and guidance documents.

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/Non-Risk

This position requires a security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of *highly sensitive* information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

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 **August 29, 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-15-2024-DMPP** in the email subject line.

Announcement Contact

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

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

FDA is an equal opportunity employer.