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 Surveillance and Epidemiology (OSE)

Application Period: July 2, 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: Regulatory Policy Analyst

Series: AD-0601

Location(s): Silver Spring, Maryland

Salary: Starting at 139,395

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: Will not be paid.

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 that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than

18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

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 Surveillance and Epidemiology (OSE) is responsible for the detection, assessment, prevention, and management of the risks related to medications to ensure that they be relied upon to treat disease and improve health.

Duties/Responsibilities

As a **Regulatory Policy Analyst,** the incumbent will participate on projects related to RAS, which includes the review of current Manuals on Policies and Procedures (MaPPs), regulations, and delegations of authority to provide regulatory advice and guidance for industry. Specific duties include the following:

- Serves as a recognized authority in the area of postmarketing drug safety policy, and applies expert knowledge of OSE, CDER, and FDA programs and procedures.
- Advises OSE Management Team on complex or precedent-setting issues, including amendments to laws, regulations and policies related to drug safety, and provides written analyses of and recommendations based on FDA technical statutes, regulations, policies, and procedures.
- Reviews, summarizes, and responds to inquiries, requests for waivers, and correspondence related to postmarketing reporting regulations, policy, and guidance.
- Responds to the Office of Regulatory Policy (ORP) consults related to Drug Safety Citizen Petitions. Develops regulatory written products that articulate, interpret, and explain complex Drug Safety programs and public health research findings.
- Performs final review of materials for technical accuracy, style, proper organization, emphasis, editorial aspects and consistency with FDA policy and regulations before release.
- Leads and contributes to projects to revise or develop FDA laws, regulations, guidance documents, policies, and procedures, CDER initiatives or other activities relevant to postmarketing drug safety.
- Resolves regulatory disagreements related to drug safety through negotiations, and articulate any consensus reached through this process.
- Evaluates the content of new or modified legislation and policies to project the impact upon specific drug programs. Provide technical guidance to OSE colleagues in interpreting the intent of laws, FDA policies, regulations, guidance documents, and/or MAPPs.

- Conducts research using regulatory references and other resources independently as relevant to document preparation, and to cite references, regulations, and resources appropriately.
- Participates in collaborative working groups of scientific, regulatory, and legal experts to develop policy recommendations regarding drug safety.
- Mentors and trains members of the Office on significant regulatory concepts, established methodologies, procedures, guidelines, and policies related to drug safety.
- Maintains a working knowledge of the regulated industry as it relates to postmarketing drug safety to provide policy guidance to OSE and other Center contacts (OND, OGD, OC, OPQ).
- Provides consultation, opinion, and recommendations relating to postmarketing drug safety, and meets with representatives of regulated firms with challenges in the area of postmarketing drug safety and maintains continuing contact with other organizations within the Center, the Agency, State and local governments, and other international regulatory agencies (e.g., The International Council for Harmonisation (ICH), World Health Organization (WHO), etc.) and competent authorities.
- Attends meetings within the professional community or the regulated industry both inside and outside the Federal government and addresses various professional groups with representatives from pharmaceutical companies, academia, healthcare organizations, and patient advocacy groups on the area of postmarketing drug safety.
- Identifies novel approaches for use of existing or new information technology tools to support the regulatory projects, programs, and administrative functions of the Office.

Supervisory Responsibilities: None

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, candidate 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 Series, 0601: Degree: 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 U.S. Department of Education at the time the degree was obtained. See: OPM Occupational Series Qualification Requirements.

Position's Desired Skills, Experience, or Education:

Our ideal candidate will possess:

- Ability to apply knowledge of basic legislation, laws, precedents, and regulations which govern the activities of the Office/Center/Agency, including postmarketing safety policy Office of Surveillance and Epidemiology.
- Demonstrated experience applying post-marketing safety knowledge to all occupation-related duties and
- responsibilities. rough knowledge of, as well as the intent of, enabling, legislation, policies, implementing regulations and procedures, policies, and guidelines, scientific information, organizational structures and interrelationships of compliance organizations and programs with each other in relation to the area of assigned responsibility.
- Ability to utilize compliance-focused regulations and laws cited within the CFR and the Federal Food, Drug
  and Cosmetic Act to address compliance issues.

- Demonstrated experience applying methods, practices and techniques of policy development and project management to manage regulatory projects and resources. Ability to prioritize workload, set and meet goals and objectives.
- Demonstrated experience applying of a wide range of qualitative and quantitative methods for assessment and analysis leading to evaluation and improvement of complex projects and processes.
- Experience utilizing analytical ability sufficiently to provide the Staff Director and office senior leadership with authoritative information, analysis, advice, and assistance in the formulation and solution of major,complex, and sensitive administrative, management and program issues and problems.
- Ability to communicate, verbally and in writing. Demonstrated commitment to communicate in a timely manner.
- Ability to interface and work with staff at all levels of the organization and varying levels of domain expertise.

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 U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

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

If not previously completed, 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 these 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 to OSE-PMAS-Admin-Team@fda.hhs.gov

by **July 31, 2024.** Candidate resumes may be shared with hiring officials within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share".

Please reference Job ID: RPA-D on the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact OSE-PMAS-Admin-Team@FDA.HHS.gov.

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

FDA is an equal opportunity employer.