Title 21 Vacancy Announcement
U.S. 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: June 29, 2023 - July 14, 2023

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 Counsel

Series: AD-0301

Location(s): Silver Spring, MD

Salary: Starting at $132,368

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: 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 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 (OMPI) directs the development of medical policy pertaining to drug development, drug approval, bioresearch monitoring, human subject protection, and post market surveillance processes in collaboration with program areas and coordinating committees.

The Division of Clinical Trial Quality (DCTQ) develops and implements policies and initiatives to promote the quality of clinical investigations, particularly with respect to human subject protections and data integrity.

Duties/Responsibilities

As a **Regulatory Counsel**, the incumbent is responsible for ensuring that regulations and policies developed in the assigned areas are consistent with statutory requirements and existing policy, including needs justification and that scientific and regulatory decisions have been appropriately documented. Performs duties that include resolving a broad range of regulatory, scientific, and technical issues concerning the application of FDA's enabling legislation, pertinent regulations, and/or general legislation affecting the operation of the federal government. Assignments are often complicated by the need to research complex or controversial issues of wide public interest and to revise existing or create new innovative policies and regulations.

- Develops, revises, and provides critical input on existing or proposed policies, programs, regulations, and guidance documents involving the most complex and high priority matters, that generally affect either an entire industry or a significant sector of the regulated industry.

- Leads or works as a part of cross-discipline workgroups to develop regulations and guidance, and interfaces with personnel, including the Office of Regulatory Policy (ORP) and the Office of the Chief Counsel (OCC), to ensure that regulations and guidances are well-written and consistent with all applicable regulatory and scientific requirements. As appropriate, assumes primary drafting responsibility for the group work product, including synthesizing input from multiple sources to achieve comprehensive, coherent

policy.
- Leads work finalizing proposed guidances and regulations which includes reviewing, summarizing, recommending adoption or rejection of proposals, and drafting responses to public comments received.

- Advises other offices in the Center on existing and revised guidances and regulations.

- Works with staff to identify and resolve areas of disagreement within FDA and articulates policy consensus reached through this process.

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:
Regulatory Counsel – AD 0301 Series

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

Desired Education:
Our ideal candidate will possess a juris doctorate degree from an accredited institution.

Desired Professional Experience:
Our ideal candidate will possess:

- Relevant experience either developing and implementing guidances or regulations for a Federal Agency or working for an entity directly involved in pharmaceutical research.
- Demonstrated ability to identify and analyze problems, determine and weigh the relevance and accuracy of related information, evaluate solutions, and make recommendations with supporting rationales.
- Demonstrated ability to communicate well orally and in writing.
- Demonstrated ability to work successfully with staff at all levels of the organization and varying levels of domain expertise, and to collaborate across boundaries to build strategic relationships and achieve common goals.
- Demonstrated ability to work independently and as a contributing collaborative team member.
- Demonstrated ability to organize time effectively, determine priorities, and move work forward efficiently.

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

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 maybe 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 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 14, 2023,** to: Tammy.Sauter@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.

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, writing 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 Tammy Sauter, Lead Management and Program Analyst at Tammy.Sauter@fda.hhs.gov.

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