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 Regulatory Policy (ORP)

Application Period: August 30, 2022 – September 30, 2022

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:
$103,690 (Band C) or
$122,530 (Band D)

Work Schedule: Full Time

Cures Band(s): Band C/D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

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 mission of the Office of Regulatory Policy (ORP) is to provide Center oversight and leadership in the development of regulations, policies, procedures, and guidance's that affect the drug approval process, and in the development of new legislation. Also, ORP manages the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and Food and Drug Administration's public disclosure regulations.

Duties/Responsibilities

As a **Regulatory Counsel** in the Divisions of Regulatory Policy (DRP) I-IV in the Office of Regulatory Policy (ORP), the incumbent is responsible for writing regulations, preparing responses to citizen petitions, petitions for stay of action, and/or petitions for reconsideration; drafting and commenting on legislation; and providing advice on the interpretations of the laws, regulations, and policies applicable to the FDA.

Band C:
Conducts sophisticated analyses of complex regulatory and policy issues and provides advice to CDER staff in carrying out its regulatory mission as a regulatory resource to the issuance of FDA regulations and petition responses.

Band D:

- Meets duties and responsibilities outlined in Band C above.
- Provides technical advice and guidance to more junior Regulatory Counsels.
- Works on complex and difficult assignments of national scope and significance. Assumes responsibility for ensuring that regulations and policies developed in the assigned areas are consistent with the statutory requirements and existing policy, that is justified, and adequately supported by appropriate analysis including adequate scientific and medical analyses when required.
- Performs duties that include resolving a broad range of issues concerning the application of any of FDA's enabling statutes, pertinent regulations, and/or general laws affecting the operation of the federal government. Assignments are often complicated by the need to research complex or controversial regulatory and policy issues of wide public interest and to revise existing or create innovative policies and regulations.

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 is required.
- Financial Disclosure is required.
- Ethics Clearance is 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. Please refer to the Ethics Clearance Requirements section.
- Background Investigation/Security Clearance Requirements: Non-Sensitive/Moderate Risk.

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

Degree: A juris doctorate degree from an accredited institution of higher learning. For more information please see: OPM Occupational Series Qualification Requirements.

Professional Experience:

Our ideal candidate will possess:

At least three years (Band C) to five years (Band D) of experience in handling regulatory issues (i.e., in a firm, regulated industry or government setting) such as by writing or commenting on regulations; preparing or responding to petitions; drafting or commenting on legislation; or

providing advice on the interpretations of laws, regulations and policies.

Desired Professional Experience:
Our ideal candidate will possess:

Band C:

- Demonstrated experience and knowledge of federal regulatory programs is highly desired.

OR

Band D:

- Demonstrated experience and knowledge of federal regulatory programs and FDCA or drug regulatory program experience is highly desired.

Band C and Band D:

- Demonstrated experience and ability to identify and analyze problems; weighing the relevance and accuracy of information; generating and evaluating alternative solutions; and making recommendations.
- Possession of experience and knowledge in regulatory practices, policies, and procedures is highly desired.
- Ability to organize time effectively, determine priorities, and move work forward.
- Ability to work independently and as a contributing, collaborative team member.
- Ability to communicate orally and in writing and work with staff at all levels of the organization and varying levels of domain expertise.
- Demonstrated experience and skill to collaborate across boundaries to build strategic relationships and to achieve common goals.

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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

Ethics Clearance Requirements

This position requires 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 **September 30, 2022**, to: CDER-ORP-Cures-Hiring@fda.hhs.gov. On the subject line, please reference "**Regulatory Counsel Band C**" or "**Regulatory Counsel Band D**." 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". For questions, please contact CDER-ORP-Cures-Hiring@fda.hhs.gov.

How I Will Be Evaluated

Candidates may be evaluated based on an interview, 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 CDER-ORP-Cures-Hiring@fda.hhs.gov.

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

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