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 Compliance (OC)
Immediate Office (IO)

Application Period: April 21, 2023 – May 5, 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: Deputy Super Office Director (Supervisory Regulatory Counsel)

Series: AD-0301

Location(s): Silver Spring, MD

Salary: Starting at: $213,491

Work Schedule: Full-Time

Cures Band(s): Band G

Full Performance Band Level: Band G

Travel Requirements: 25% or less

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 compensated 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 Compliance (OC) is to shield the public from poor-quality, unsafe, and ineffective drugs through proactive compliance strategies and risk-based enforcement actions. CDER Compliance strives to be a model of efficiency, innovation, and organizational excellence. CDER Compliance makes strategic and risk-based decisions that are guided by law and science to communicate clearly with stakeholders, foster global collaboration, promote voluntary compliance, and take decisive action.

Duties/Responsibilities

As the **Deputy Super Office Director (Supervisory Regulatory Counsel)**, reporting to the Deputy Director of the Office of Compliance (CDER OC), the incumbent will share the responsibility for the management and direction of a multi-disciplinary staff of more than 400 scientific and regulatory professionals engaged in planning, executing, and administering a broad range of national programs related to protecting the health of patients and consumers from risks associated with violations of federal drug law and regulation.

- Responsible for the development and implementation of proactive and risk-based compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's drug supply.
- Strategically oversees and implements FDA and Center compliance programs and projects to identify, assess, and prioritize the public health significance of legal violations presented throughout the drug lifecycle. Develops and implements innovative enforcement strategies and risk-based decision-making to reduce public health risk by ensuring that marketed drugs are of high quality and integrity, properly labeled, safe, pure, and meet applicable drug approval requirements.
- Develops comprehensive policy and procedural guidelines for handling legal actions related to human drugs. Reviews and approves legal approaches and actions in cases, particularly those that are controversial, precedent setting, or otherwise significant cases.
- Represents the Director/Office in meetings, discussions, and conferences with senior Agency and Departmental officials, regulated industry representatives, the medical, scientific, and academic communities, national and international scientific and health related professional organizations, Congress, and representatives from other Federal, state, local and international governmental agencies to present and explain Office activities, actions, plans, and policies.
- Serves as the lead on special projects and activities of interest and concern to the Office Director that involve sensitive and controversial problems, issues, or actions related to policy and/or program matters which may result from a public health emergency or may have congressional interest.

Supervisory Responsibilities:

Manages one or more portfolios and provides leadership and direction for multiple, smaller program offices in coordination with the Super Office Director. Directly supervises the Super Office's Senior Medical Officer and Senior Program Manager. Shares responsibility with the Super Office Director to provide overall program direction to subordinate Sub-Offices and Divisions and through the responsible managers of these Offices and Divisions. Provides direction to a budgeted staff of 436 employees including scientific, medical, legal, professional, technical, administrative, and clerical personnel ranging in pay scale from Titles 42 and GS 15 Supervisory positions to entry levels, as well as scientists and physicians hired under Title 42 and Title 38.

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.

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:

Deputy Super Office Director (Supervisory Regulatory Counsel) Series, AD-0301:
Degree: A juris doctorate degree from an accredited institution of higher learning.

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

Desired Professional Experience:
Our ideal candidate will possess:

- A law degree from an accredited institution.
- Significant experience in managing large organizations with a regulatory, compliance or law enforcement mission, including a demonstrated ability to:
  - Produce results and lead change.
  - Lead people: Build coalitions and collaborate across boundaries to achieve common goals.
- Knowledge of and demonstrated experience with the content and working of the Food, Drug and Cosmetic Act and related regulations applicable to human drugs that are administered by the Food and Drug Administration, as well as related Federal, civil, and criminal law and adjudication processes and procedures.
- Demonstrated ability to identify and analyze complex problems, generate, and evaluate alternative solutions, and make evidence-based decisions.
  Knowledge of and demonstrated experience with the risk management associated with the production and marketing of human drugs, policy development, strategic planning, and implementation, as well as the ability to converse with stakeholders in the associated legal, scientific, and engineering fields.

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/High-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 qualifications is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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 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 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 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

All qualified candidates should submit their resume with cover letter and transcripts in PDF format by **May 5, 2023,** to: FDACDEROC_Recuit@fda.hhs.gov. 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 submit your inquiry with email subject title ***“CDER-OC-Deputy Super Office Director”*** when applying or submitting questions.

Announcement Contact

For questions regarding this Cures position, please contact FDACDEROC_Recruit@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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