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 Compliance (OC)
Office of Drug Security, Integrity, and Response (ODSIR)
Division of Supply Chain Integrity (DSCI)
Immediate Office (IO)

Application: September 10,2024 – September 24,2024

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 Specialist

Series: AD-0696

Location(s): Silver Spring, MD

Salary: Starting at $139,395 - $191,900

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 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Compliance (OC) is to shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions. CDER OC strives to be a model of efficiency, innovation, and operational excellence. Guided by law and science, the Office makes strategic and risk-based decisions, communicates clearly with all stakeholders, fosters global collaboration, promotes voluntary compliance, and takes decisive action.

The Office of Drug Security, Integrity, and Response (ODSIR) develops policies and compliance strategies for protecting the public health by assuring drug product quality and supply chain integrity. ODSIR coordinates evaluation and classification of drug recalls and provides Center coordination with field Offices for implementation of recalls and monitors resolution of related compliance issues. They also ensure integrity of imported and exported drugs by assuring compliance with applicable legal requirements.

The Division of Supply Chain Integrity (DSCI)'s mission is to reduce threats to the global drug supply chain by facilitating risk-based regulatory compliance actions based on science and law in a timely, high-quality, and efficient manner, increased transparency and accountability, effective enforcement, and collaboration with stakeholders to promote proactive vigilance and voluntary compliance.

Duties/Responsibilities

As **a Regulatory Specialist**, the incumbent provides assistance to the DSCI Division Director in the management and direction of the development and implementation of the Agency's human drug recalls, and supply chain integrity compliance and enforcement programs. The incumbent advises and makes recommendations to subordinate Branch Chiefs regarding the oversight of immediate division operations and coordinates development of short/long term goals, policy, guidance, and innovative compliance strategies.

- Supports the Division Director in oversight and management of the multi-disciplinary programs for the Division.
- Develops and oversees of policy implementation, surveillance activities, compliance strategies, regulatory actions and enforcement actions pertaining to the Drug Supply Chain Security Act (DSCSA), including the development, implementation, and oversight of federal Good Distribution Practice standards and drug incidents and recalls and shortages under the Federal Food, Drug, and Cosmetic Act and other applicable laws and regulations.
- Manages and coordinates of operational issues pertaining to drug supply chain, incidents, recalls and shortages for the Division of Supply Chain Integrity, including triaging of consults from FDA's Drug Shortages Staff as well as compliance evaluation

and actions by the Office of Compliance's Office of Manufacturing Quality and ORA Field Offices.

- Triages and provides recommendations concerning the DSCI incident response to urgent, emerging, and evolving public health issues related to FDA approved drugs, counterfeit and substandard drugs, and other unapproved drug products. This includes providing direction to the Supply Chain Security Branch and Incidents, Recalls, and Shortages Branch efforts which coordinates Office of Compliance efforts to investigate and evaluate incidents to contain the public health exposure to potentially harmful drugs.
- Works closely with other CDER Offices, including CDER's Counterterrorism and Emergency Coordination Staff, as well as the Agency's Office of Emergency Operations to ensure DSCI's works seamlessly with internal stakeholders to address incidents response.
- Supports the development of comprehensive policy and procedural guidelines for handling compliance and enforcement actions related to human drugs. Reviews legal actions in cases where authority has not been delegated to the field, where guidelines have not yet been established, and cases of national scope requiring headquarters coordination.
- Coordinates Division and Office of Regulatory Affairs (ORA) Field relations and provides support and guidance to field offices on case development, evaluations and regulatory actions and ensures uniform interpretation and application of standards.
- Represents the DSCI in meetings on compliance matters of major significance. Represents the Division in meetings with top level representatives of other FDA offices, FDA Centers, and Federal and State agencies to obtain their cooperation on compliance matters of mutual interest. Engages with stakeholders, including top level leaders of regulated industries to promote compliance.
- Serves as the lead on special projects and activities of interest and concern to the DSCI 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: 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.

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:

Education: A bachelor's degree or higher in quality assurance/management, data science, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food science, law or regulations, or related healthcare or science field. The degree must be from an accredited program or institution.

OR

Experience: Comparable regulatory experience or FDA regulated product lifecycle experience focused on enforcing and/or ensuring compliance with FDA laws and regulations or experience in one or more of the following: x Knowledge of the FD&C Act combined with experience in either Current Good Manufacturing Practices (cGMP), or auditing products that the FDA regulates. x Interpreting the statute, regulations, guidance, and other quality policies to assess compliance, quality, manufacturing performance, or quality management maturity. x Product development, process development, scale-up, or commercial manufacturing. x Sterility

assurance and microbiological controls.

Desired Skills, Experience, or Education:
Our ideal candidate will possess:

- Technical and scientific expertise in drug product supply chain integrity and security, incidents, recalls, shortages, and FDA laws and compliance regulations.
- Demonstrated experience applying the Food, Drug and Cosmetic (FD&C) Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities.
- Demonstrated experience evaluating and making recommendations with respect to compliance with regulations and other applicable requirements and policies.
- Demonstrated experience communicating scientific/technical information to others regarding regulatory compliance issues.
- Skills in interpreting legal and regulatory guidelines and agency policies to advise on program operations.
- Skills in providing guidance and consultation to enforce regulatory objectives.

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/Moderate Risk

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 actions.

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 **September 24, 2024**, to: CDER-OC-RECRUITMENT@fda.hhs.gov. Candidate resumes may be shared with hiring official within CDER 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**-24-1280-D** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact CDER-OC-ODSIR-RECRUITMENT@FDA.HHS.GOV.

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