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)
Incidents, Recalls, and Shortages Branch (IRSB)

Application: August 8, 2024 – August 29, 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): Remote anywhere in the U.S.

Salary: $117,962 - $164,260

Work Schedule: Full-Time

Cures Band(s): Band C

Full Performance Band Level: Band C

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 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 mission of the Office of Drug Security, Integrity, and Response (ODSIR) is to develop policies and compliance strategies for protecting the public health by assuring drug product quality and supply chain integrity; 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; Ensures 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.

The Incidents, Recalls, and Shortages Branch (IRSB) manages recalls, shortages, and incidents for human drug products in CDER. IRSB's goal is to facilitate proactive, risk-based regulatory compliance actions based on science and the law in a timely and efficient manner in order to protect the drug supply chain integrity. We aim to provide high-quality services and to promote excellence in executing regulatory and enforcement strategies through collaboration with our partners and stakeholders.

Duties/Responsibilities

As a Regulatory Specialist in the Recalls and Shortages Team in IRSB, the incumbent is responsible for the duties listed below. This position reports to the IRSB Branch Chief.

- Assesses, evaluates, and prioritizes human drug compliance issues associated with marketed product defects or quality issues that may result in product recalls, market withdrawals, or potential drug shortages.
- Informs, consults with, and advises Office management, FDA field offices, and other multidisciplinary personnel on difficult and complex regulatory, scientific and drug compliance problems and issues discovered during evaluations. In consultation with senior stadd, monitors, reviews, and prepares final reports including Agency

determinations and findings.

- Reviews and classifies recalls of human drug products regulated by CDER in alignment with Title 21 of the Code of Federal Regulations Part 7 and Chapter 7 of the Regulatory Procedures Manual. Coordinates communications and activities related to recalls between the FDA field offices and CDER OC. Coordinates review of recall-related public communications in collaboration with FDA field offices and Agency Communications Staff, as applicable.
- Provides risk communications related to recalls to internal and external stakeholders.
- Obtains technical evaluations on compounding-related issues, adulteration issues, and misbranding violations as well as health hazard evaluations from various component offices throughout the Center.
- Coordinates review of shortage proposals submitted by Industry within OC to prevent human drug shortages in collaboration with the Drug Shortage Staff (DSS). Conducts compliance shortage evaluations related to firms that may be impacted by recommendations of enforcement actions such as warning letters.
- Collaborates with branch leadership, participates, and contributes to the design, development, and implementation of IRSB strategic plans related to human drug product quality and supply chain integrity, including development and execution of policies, processes, and procedures.
- Maintains knowledge of ongoing significant scientific and regulatory/enforcement activities related to pharmaceutical product quality and distribution. May serve as a liaison to other Center/Agency staff on matters related to branch operations.
- Supports strategies and initiatives related to public health communications, participates in training, outreach, and educational events to further compliance programs, and participates in projects meant to promote human drug product quality and supply chain integrity.
- As a representative of FDA and CDER, conducts briefings, presentations, and meetings with internal stakeholders and regulated industry representatives, trade organizations, academic, health professional groups and organizations.
- Represents FDA on interagency, national, and international committees and forums and represents CDER at professional meetings with regulated industry and with Federal and State regulatory counterparts and agencies (e.g., Center for Disease Control, State Departments of Health; US Justice Department).
- Represents FDA and CDER and participates on internal and external working groups, national tasks forces, and scientific symposia, and public workshops.
- Maintains effective working relationships with internal staff and external stakeholders to promote and sustain programs.

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:

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:

- Knowledge of the Food Drug and Cosmetic (FD&C) Act combined with experience in either Current Good Manufacturing Practices (cGMP), or auditing products that the FDA regulates.
- Interpreting the statute, regulations, guidance, and other quality policies to assess compliance, quality, manufacturing performance, or quality management maturity.
- Product development, process development, scale-up, or commercial manufacturing.
- Sterility assurance and microbiological controls.

Desired Skills & Experience:
Our ideal candidate will possess:

- Demonstrated experience and ability to review, assess, and enforce laws and regulations to protect consumers from foods, drugs, cosmetics, fabrics, toys, equipment, and household products that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.
- Ability to apply knowledge of enabling legislation, policies, implementing regulations and procedures, organizational structures, and interrelationships of compliance organizations and programs with each other in relation to area of responsibility.
- Ability to apply knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques.
- Ability to apply knowledge of written and verbal communication practices and principles to prepare and present written reports, findings, and recommendations. Demonstrated experience and ability to communicate scientific/technical information to others regarding regulatory compliance issues.
- Experience applying the Federal Food, Drug, and Cosmetic (FD&C) Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities.
- Demonstrated experience and ability to review, evaluate and make recommendations with respect to compliance with regulations and other applicable requirements and policies.
- Ability to interpret legal or regulatory guidelines and Agency policies to advise on program operations.
- Ability to provide guidance and consultation to enforce regulatory objectives.

Desired Professional Experience:
Our ideal candidate will possess:

- A strong background in review and management of drug product recalls and shortages. Background in data analytics, data management, data visualization, and IT systems management is preferred.
- Experience applying the Food, Drug and Cosmetic Act (FDCA) to drug compliance/enforcement activities, and related regulatory and quality assurance activities is beneficial.
- Experience evaluating and making recommendations with respect to compliance with regulations and other applicable requirements and policies.
- Experience communicating scientific/technical information to others regarding regulatory compliance issues.
- Skilled in interpreting regulatory guidelines and agency policies to advise on program operations.
- Skilled 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 **August 29,2024** to: CDER-OC-ODSIR-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". For questions, please contact CDER-OC-ODSIR-Recruitment@fda.hhs.gov.

Please reference Job Reference ID: T-24-1213-C.

Announcement Contact

For questions regarding this Cures position, please contact CDER-OC-ODSIR-Recruitment@fda.hhs.gov.

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