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 Global Drug Distribution and Policy (DGDDP)
Imports Compliance Branch (ICB)
Multiple selections can be made from this announcement

Application Period: April 22, 2024 - May 6, 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: Starting at
$82,764-$109, 506 (Band A)
$99, 200-$133,845 (Band B)
$117, 962-$164, 260 (Band C)

Work Schedule: Full-Time

Cures Band(s): Band A/B/C

Travel Requirements: 25% or less

Full Performance Band Level: Band C

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. CDER is looking for leaders with a commitment to scientific excellence and innovative thinking to lead a dynamic and diverse organization.

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 Global Drug Distribution and Policy (DGDDP) shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions. DGDDP serves as CDER's focal point for Imports surveillance, compliance, policy and analytics and Exports surveillance, compliance, and policy.

Imports Compliance Branch (ICB) serves as FDA and CDER's focal point for operational, compliance and policy issues related to the import of drugs including operation, surveillance, sampling, and work planning. ICB coordinates with the Office of Regulatory Affairs (ORA) on policies and programs related to import operations. And provides assistance and guidance to the field and consults on import issues and problems related to specific products offered for import.

Duties/Responsibilities

As a **Regulatory Specialist,** the incumbent is responsible for the Imports Compliance Branch (ICB), Division of Global Drug Distribution and Policy (DGDDP) under the Office of Drugs Security, Integrity, and Response (ODSIR). This position reports to the ICB Branch Chief.

- Provides necessary coordination, planning, consultations, opinions, and endorsements regarding the area of his or her regulatory subject matter.

- Coordinates on shortage issues involving Import alert carve outs, issuance of export certificates for human drugs and Current Good Manufacturing Practices (CGMP) declarations, facilitate drug import activities, and access incoming shipments of drugs.
- Supports the development and implementation of statutory programs and industry communication and outreach on drug imports and exports issues. Assists with review and evaluation of regulatory discretion submissions to support the determination on whether the data submitted consideration of enforcement discretion for importation.
- Assists with evaluation of importation of drugs to determine necessary action related to incidences, Rapid Alert Notifications (RANs), and other Compliance actions as they arise.
- Supports internal and external working groups, tasks forces, scientific symposia, and public workshops as needed.

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:

Regulatory Specialist, AD-0696:

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:

- 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 imports and/or data analytics, data management, statistical analysis, data visualization, and IT systems development 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/Low Risk (Band A/B/C)

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 **May 6, 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”.

Announcement Contact

For questions regarding this Cures position, please contact **Monica.Lewis@fda.hhs.gov**.

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

FDA is an equal opportunity employer.