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 Compounding Quality and Compliance (OCQC)
Divisions of Compounding 1 and 2 (DC1 & DC2)
Multiple selections

Application Period: June 10, 2024 – June 28, 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:
$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

Full Performance Band Level: Band C

Travel Requirements: Up to 75% travel

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 and prescription drugs, including biological therapeutics and generic drugs.

The mission of CDER's 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 Compounding Quality and Compliance (OCQC) is responsible for the development and implementation of compliance strategies, programs, and policies to protect the public health minimizing exposure to unsafe, ineffective, and poor-quality compounded drugs. OCQC engages in strategic risk-based compliance and regulatory activities and coordinates responses to reports, complaints and incidents associated with compounded drugs that threaten patient safety. It oversees the development of risk-based surveillance, follow-up or for-cause inspection assignments and inquiries, and technical support for judicial actions related to compounded drugs.

The Divisions of Compounding I and II are responsible for the development and implementation of compliance strategies, programs, and policies to protect the public health and minimizing exposure to unsafe, ineffective, and poor-quality compounded drugs. Each division engages in strategic risk-based compliance and regulatory activities and coordinates responses to reports, complaints and incidents associated with compounded drugs that threaten patient safety. The divisions oversee the development of risk-based surveillance, follow-up or for-cause inspection assignments and inquiries, and oversee technical support for judicial actions related to compounded drugs.

Duties/Responsibilities

As a **Regulatory Specialist**, the incumbent is responsible for supporting a program function on a team that resides within a Branch in one of two Divisions of Compounding. The work of the Divisions includes performing investigations involving complaints and injuries or deaths associated with compounding drug products regulated by the FDA.

- Analyzes information, applying scientific and regulatory knowledge, performing technical investigations requiring coordination, insight, and knowledge in application of procedures and processes involving compliance, inspections, regulation, and enforcement actions relating to compounding drug products.

Band A:

- Participates in technical reviews and evaluating compounders where new or unusual

features are present and facility inspections of compounders including facilities operating under section 503B of the Food, Drug, and Cosmetic (FD&C) Act.

- Reviews data and information gathered during inspections and investigations compounding facilities and gathers information to support informal hearings with non-compliant establishments. Reviews proposed legal actions from ORA, CDER Recalls and other offices to evaluate conformance with enforcement policy, regulatory objectives, jurisdiction, and adequacy of evidence.

Band B:

- Meets duties and responsibilities outlined in Band A above.
- Conducts activities in critical strategic, risk-based compliance and regulatory actions to minimize consumer exposure to unsafe, ineffective, and poor-quality compounded drug products. These activities include independently performing investigations of complaints that trace back to investigations of injuries or deaths attributable to compounding drug products regulated by the FDA. Plans and decides how the investigation will be completed, and what reporting is required.

Band C:

- Meets duties and responsibilities outlined in Band B above.
- Performs substantive activities in critical risk-based compliance and regulatory areas to minimize consumer exposure to unsafe, ineffective, and poor-quality compounded drug products. These activities include conducting difficult, complex, controversial, and precedent setting evaluations of a compounding facility's compliance with established Federal laws and regulations to include root cause analyses for adequacy and impact on the quality of the drugs produced by the facility and developing guidance and policy documents to encourage and attain voluntary compliance.

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 Series:

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:

- Full working knowledge of nearly all aspects of occupational specialty. May have a working knowledge in an emerging field.
- 2+ years of technical experience in a specific scientific area.
- Knowledge of the Food, Drug and Cosmetic (FD&C) Act, implementing rules and regulations, and precedents applied to area of assigned responsibility.
- Knowledge of industry/commodities representing area for which responsible, of the raw materials, products, Production practices and related problems associated with industries/commodities which make up area of assigned responsibility.
- Knowledge of and skill in selecting, adapting, and applying basic investigative methods.
- Knowledge of policies, patterns, and practices of firms as those relate to applicable compliance programs. This knowledge is necessary to understand extensive, complex, and complicated production and operations, and to recognize any discrepancies or inconsistencies between information reported and made available and the true nature of manufacturer being inspected or investigated.

Desired Professional Experience:
Our ideal candidate will possess:

- Knowledge of the 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.
- Knowledge of the application of the Food, Drug, and Cosmetic (FD&C) Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities.
- Knowledge of how to evaluate and make recommendations with respect to compliance with regulations and other applicable requirements and policies.
- Ability to communicate scientific/technical information to others regarding regulatory compliance issues.
- Ability to interpret legal or regulatory guidelines and Agency policies to advise on program operations.

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-Medium 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 **June 28, 2024**, to cder-oc-compounding-recruitment@fda.hhs.gov.

Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please include Position /Office/Application Period in the Subject line of the email (i.e., CURES Regulatory Specialist Band A/B/C Office of Compliance/ Office of Compounding Quality and Compliance/Application Period 06/10/24 – 06/28/24) and provide this information in your cover letter.

Announcement Contact

For questions regarding this Cures position, please contact cder-oc-compounding-recruitment@fda.hhs.gov.

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