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)
Office of Manufacturing Quality (OMQ)

Application Period: April 11, 2023 - May 11, 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: Consumer Safety Officer

Series: AD-0696

Location(s): Silver Spring, MD

Salary: $112,015 - $171,576

Work Schedule: Full-Time (Telework Eligible)

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) 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 Center for Drug Evaluation and Research (CDER) is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs (OTC).

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 function of the Office of Manufacturing Quality (OMQ) is to develop and implement compliance and enforcement policies and actions to protect patients from firms whose quality standards and practices may pose a significant risk to public health.

Duties/Responsibilities

As a **Consumer Safety Officer,** the incumbent reviews recommendations for potential administrative and judicial actions based on adulteration charges under the Food Drug & Cosmetic (FD&C) Act to ensure consistency and adherence to FDA policy. Provides enforcement decision and compliance strategies based on review of evidence of violations, compliance policy, public health risks, and availability.

- Provides scientific and technical input on compliance issues and in regulatory meetings to ensure consistency of interpretation of Current Good Manufacturing Practices (CGMPs).
- Provides expertise to address significant manufacturing problems or quality defects.
- Reviews recommendations for potential administrative and judicial actions based on adulteration charges under the FD&C Act to ensure consistency and adherence to FDA policy, provide enforcement decision and compliance strategies based on review of evidence of violations, compliance policy, public health risks, and availability.
- Provides an accurate assessment of the state of compliance of a firm or corporation on regulatory compliance and enforcement and confers with and advises the FDA Office of the Commissioner, CDER Center and other Office Directors on potential issues and impacts associated with drug manufacturing and medical product consistency.

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.

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:

Consumer Safety Officer Series– AD-0696

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

Desired Education:

Our ideal candidate will possess:

A bachelor's or graduate degree/higher level degree in the biological sciences (see requirements above), or chemical or biomedical engineering that meets this requirement A M.S. or Ph.D. that supports drug Current Good Manufacturing Practice (CGMP) experience and those with manufacturing, quality and laboratory systems experience preferred.

Professional Experience:

Our ideal candidate will possess:

- Experience in applying the Food, Drug and Cosmetic (FD&C) Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities. Examples in applying and demonstrating knowledge of different sections of the FD&C Act and the Code of Federal Regulations enforced by the FDA should be provided.
- Experience in evaluating and making recommendations with respect to compliance with regulations and other applicable requirements and policies related to CGMPs of medical products.
- Documented experience in more than one of the following areas: (a) aseptic drug manufacturing operations, including but not limited to performing media fills, smoke studies, terminal sterilization validation, failure investigations (be specific about equipment used and role in these activities) or (b) specialized laboratory and/or production experience- type of equipment testing, the role and direct experience in this area (e.g., description of software, version, role-oversight responsibility or direct hands on experience and level of expertise) or (c) experience in cleaning validation. Please provide examples.
- Experience in evaluating and making recommendations with respect to compliance regulations and other applicable requirements and policies related to drug current good manufacturing practices (CGMPs). Identify the application of concepts outlined by the agency in published guidance documents (e.g., Guidance for Out of Specifications, Guidance for Process Validation, Aseptic Process Guidance, Data Integrity Guidance, Quality System Guidance). Please provide specific examples.
- Experience in serving as a technical scientific lead in one or more major CGMP areas and performs substantive work with a multiplicity of unprecedented and complex scientific topics, including, but not limited to human drugs, adulteration provision of the FD&C Act, emerging technologies, new regulations, and scientific policies.
- Demonstrated skill in providing expert advice, guidance and recommendations on drug compliance policies, programs, processes, and proceedings as it relates medical products and skill in interpreting legal or regulatory guidelines and agency policies to advise on program operations.

**Please indicate in your resume where you have this gained this experience*. **

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-Critical Sensitive/Moderate 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 qualification 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 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

All qualified candidates should submit a curriculum vitae (CV) and cover letter describing why you are uniquely qualified for this position, including how you possess the desired experience and qualifications identified above by **May 11, 2023,** to CDEROC_recruit@fda.hhs.gov. Please include ***CURES Consumer Safety Officer - Band C/Office of Compliance/Office of Manufacturing Quality*** */ (04/11/23 – 05/11/23*) as well as including this information in your cover letter.

Candidate resumes may be shared with hiring officials 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”.

Announcement Contact

For questions regarding this Cures position, please contact CDER OC PMAS at CDEROC_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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