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)

Application Period: February 14, 2023 – February 24, 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 (Special Assistant) **Series:** AD-0696

Location(s): Silver Spring, MD **Salary:** Starting at $126,233

Work Schedule: Full Time

Cures Band(s): Band D **Full Performance Band Level:** Band D

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 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 Compounding Quality and Compliance (OCQC) aims to protect patients from unsafe, ineffective, and poor-quality compounded drugs, while preserving access to lawfully marketed compounded drugs for patients who have a medical need for them. OCQC works to protect consumers from unsafe compounded drugs, develop and implement the Compounding Quality Center of Excellence focused on improving the quality of compounded drugs, and develop and implement policies and compliance strategies to protect the public health by helping assure the quality of compounded drugs.

The Consumer Safety Officer (Special Assistant) is in a unique position to address overarching issues that impact the three (3) divisions and six (6) branches of OCQC, leading the development and implementing projects and initiatives that cut across the office.

Duties/Responsibilities

As a Consumer Safety Officer (Special Assistant) in the Office of Compounding and Quality Compliance (OCQC) and the Immediate Office, the incumbent will be responsible for developing and implementing compliance strategies, programs, policies, and communications for protecting the public health that minimize exposure to unsafe, ineffective, and poor-quality compounded drug products while preserving access to lawfully marketed compounded drugs for patients who have a medical need for them.

- Works closely with Office Director and Office Deputy Director to develop assignments, projects initiatives and responses to urgent, controversial, high profile cross cutting requests, involving compounded drugs. Because of the broad compliance, policy, and enforcement responsibilities of the Office of Compounding and Quality Compliance (OCQC), the workload is variable, crosscutting and often complex, requiring directed and urgent action.

- Identifies and assesses emerging, standing, or precedent-setting issues and their potential or real impact on Office procedures, policies, activities, and resources that impact all OCQC, the three (3) divisions and six (6) branches. Makes decisions concerning work priorities; deciding which issues must be addressed immediately and reprioritizing current work. Monitors the workflow to see that the set priorities are met.

- Performs, facilitates, or leads special assignments, projects, and initiatives on matters that cross OCQC such as projects and initiatives addressing the active pharmaceutical

ingredients (APIs) used to compound drugs. For example, this initiative addressing the use of APIs by compounders requires consensus and collaboration among the three (3) divisions on potential adulteration issues, misbranding and the conditions of sections 503A and 503B of the Federal Food, Drug, and Cosmetic (FD&C) Act as well as policy and outreach implications. As the compounding program evolves and matures, additional complex compounding compliance issues involving multiple entities throughout the office, Agency, government, Congress, and are driven by the need to protect public health will arise. After consensus within the office, assignments then often involve multiple inter-personal contacts within Agency and FDA, Federal, local health authorities, the regulated industry, healthcare professionals and the public for input and implementation.

- Research appropriate sources to develop briefing papers, projects, and initiatives and weighs the probable consequences of various approaches and provides recommendations to high level officials.

- Keeps abreast of new legislature, regulations, and policy that may impact OCQC activities, programs, and initiatives. Examines the impact between these future changes and the interface with current policies, practices, and programs. Advises the Director accordingly. Provides expert advice on policy and procedure to the Director. Develops and implements new policies and procedures and identifies critical initiatives as needed.

- Interacts with a variety of technical, scientific, public health, regulatory and administrative professionals on OCQC issues and policies across the Agency, other governmental organizations, the national and international pharmaceutical industry, and public and private entity representatives.

- Researches and prepares written and oral reports on OCQC activities throughout the Office and Agency. Prepares studies on a variety of topics including OCQC legislation, policies, projects, and special initiatives. Monitors Compounding activities and attends to emerging problems or issues that affect the direction or outcome of OCQC goals and objectives. Develops solutions or recommendations to modify or change the approach if needed and presents findings to senior management.

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 supervisory 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, AD-0696 Series
Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Occupational Requirements (IOR) for Consumer Safety Series, 0696.

Desired Education: N/A

Professional Experience: N/A

Desired Professional Experience:
Our ideal candidate will possess:
- Experience and ability to apply the Food, Drug and Cosmetic (FD&C) Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities.

- Experience and ability to evaluate and make recommendations with respect to compliance with regulations and other applicable requirements and policies.
- Experience and 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.
- Ability to provide 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 U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/High 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

Submit resume with cover letter and transcripts by **February 24, 2023** to: CDER-OC-OCQC-RECRUITMENT@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (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 PMAS OCQC Team at CDER-OC-OCQC-RECRUITMENT@fda.hhs.gov. Please reference ***"Special Assistant for OCQC"*** in the subject when applying or submitting questions.

Announcement Contact

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

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

FDA is an equal opportunity employer.