



**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)**  
**Immediate Office (IO)**

**Application Period:** 5/2/2022 – 5/27/2022

**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:** Senior Consumer Safety Officer

**Series:** AD-0696

**Location(s):** Anywhere in the U.S.

**Salary:** Starting at \$148,484

**Work Schedule:** Full Time

**Cures Band(s):** Band E

**Full Performance Band Level:** Band E

**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 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.

## Duties/Responsibilities

As the **Senior Consumer Safety Officer** in the Immediate Office of the Office of Compliance (OC), the incumbent plans, develops, and directs compliance and enforcement strategies that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's drug supply, with specific respect to the the planning, coordination, and implementation of major agency programs of national scope relating to pharmaceutical supply chain and risk management activities.

Oversees the agency's development of policy and standards regarding implementation of the congressionally mandated Drug Supply Chain Security Act (DSCSA), which outlines steps to build an electronic, interoperable system by 2023 to identify and trace certain prescription drugs as they are distributed in the United States.

Manages projects and cross-cutting initiatives for OC. Participates with OC leadership in developing and organizing policies and projects and other related concerns for the management of assigned programs.

Participates in the development of new drug supply chain surveillance, policy, and/or enforcement plans, schedules, or methods to accommodate changing program requirements. Identifies objectives based on an analysis of interrelated issues of effectiveness, efficiency and productivity of substantive mission-oriented programs. Determines approach to achieve objectives, identifies specific steps, and decides on meetings, information, and other input.

Provides subject matter expertise to OC Senior Leadership to ensure that the organization meets its stated goals, and identifies areas where operational efficiency can be enhanced, or services that involve the introduction or refinement of automation. Reviews productivity in all areas, monitors problem areas, and oversees implementation of solutions, where appropriate, to increase the organization's resources or effectiveness.

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**

Degree: Bachelor’s or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

OR

Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education. For more information, please visit: [OPM Occupational Series Qualification Requirements](#).

Desired Education: n/a

**Professional Experience:**

Our ideal candidate will possess: Qualifying experience involves enforcing 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.

**Desired Professional Experience:**

Our ideal candidate will possess:

- Demonstrated experience in identifying, articulating, addressing, and resolving unique, far-reaching, and/or previously unresolved and precedent-setting problems and complex issues.
- Demonstrated experience working with the Food, Drug & Cosmetic (FD&C) Act, and with key programs of CDER and the Office of Compliance.
- Established experience in providing Program and scientific and regulatory advice and guidance.
- Demonstrated ability to communicate, verbally and in writing, and work with staff at all levels of the organization and varying levels of domain expertise; excellent listening skills and a commitment to communicate in a timely manner.
- Demonstrated ability to organize time effectively, determine priorities, and move work forward.
- Established ability to work independently and as a contributing and collaborative team member.

## 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

How to Apply: Submit resume or curriculum vitae with cover letter and transcripts **in PDF format** by **May 27, 2022**, to: [cder-oc-io-pmas-pmt-io@fda.hhs.gov](mailto:cder-oc-io-pmas-pmt-io@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 the CDER OC IO PMAS Team at [cder-oc-io-pmas-pmt-io@fda.hhs.gov](mailto:cder-oc-io-pmas-pmt-io@fda.hhs.gov). Please reference **Job Reference ID**: “CDER OC IO Senior CSO Vacancy”.

## Announcement Contact

For questions regarding this Cures position, please contact CDER OC IO PMAS Team at [cder-oc-io-pmas-pmt-io@fda.hhs.gov](mailto:cder-oc-io-pmas-pmt-io@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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