



**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)**

**Application Period:** 02/10/2022-02/24/2022

**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:** Public Health Analyst (Special Assistant)

**Series:** AD-0685

**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:** 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 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.

## Duties/Responsibilities

**As a Public Health Analyst (Special Assistant)**, the incumbent serves as a Special Assistant to the ODSIR Director and addresses overreaching issues that impact the development of policies and compliance strategies protecting the public health. In this capacity, the incumbent leads the development and implements projects and initiatives that cut across the office, including those related to drug security, distribution, supply chain integrity, enforcement, and outreach. Given the nature of ODSIR's work to protect the integrity of the drug supply chain, workload is variable, crosscutting and often complex, requiring directed and urgent action.

- Identifies and assess emerging, standing or precedent-setting issues and their potential or real impact on ODSIR's procedure, policies, activities, and resources. Makes recommendations to ODSIR Director regarding work priorities for the Office, proposing which issues must be addressed immediately and reprioritizing current work to help ensure Office goals are achieved in a timely manner.
- Performs, facilitates, or leads special assignments, which includes data calls and other requests for information, while others may require immediate attention to address situations that develop in critical circumstances or come up in an emergency. These are often complex issues that may involve multiple entities within the Agency, government, Congress, and are driven by the need to protect public health. Assignments may involve multiple inter-personal contacts within Agency and FDA, Federal, State, and local health authorities, the regulated industry, health professionals and the public.
- Research appropriate sources to develop briefing papers, weighs the probable consequences of various approaches and provides recommendations to high-level officials.
- Keeps abreast of new legislature, rules, regulations that may impact ODSIR Compliance activities, programs, and initiatives. Examines the impact between these future changes and the interface with current policies, practices, and programs. Develops and implements new policies and procedures and identifies critical initiatives as needed. Interacts with a variety of technical, scientific, and administrative professionals on ODSIR Compliance issues and policies across the Agency, other governmental organizations, the national and international pharmaceutical industry, and public and private entity representatives.
- Evaluates, identifies, and makes recommendations to ODSIR Director for significant problems and issues in areas where nominal policy guidance exists, and requires prompt

remediation. Formulates, develops, and presents research and recommendations to ODSIR Director for appropriate follow-up action.

- Researches and prepares written and oral reports on ODSIR Compliance activities to be conveyed throughout CDER's Office of Compliance and/or throughout the Agency. Prepares studies on a variety of topics including relevant legislation, policies, projects, and special initiatives.

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:**

**Public Health Program Specialist, AD-0685 Series**

Degree: Major study in public health or other field of study with course work directly related to the work of the position to be filled. [OPM Occupational Series Qualification Requirements](#)

Or

**Specialized Experience**

- Knowledge of organizational, operational, and programmatic concepts and practices applied by public, private, or nonprofit agencies and organizations engaged in public health or other health-related activities.
- Knowledge of the methods, processes, and techniques used to develop and deliver public health or health-related programs in State and local settings.
- Knowledge of a specialized public health program.
- Knowledge of, and skill in, the application of administrative or analytical methods and techniques necessary for working within the framework of a public health or related organization and carrying out specific program functions.
- Skill in oral and written communications, gathering and conveying information, making oral presentations, and preparing reports, correspondence, and other written materials.

**Desired Education:**

A degree from an accredited institution (B.S., M.S. or other) with major study in public health or other field of study with course work directly related to the work of the position to be filled.

**Professional Experience:** N/A

**Desired Professional Experience:**

- Ability to apply the Food, Drug and Cosmetic Act, regulations, guidance, and SOPs to public health and program activities.
- Ability to analyze, evaluate, and make recommendations with respect to methods, practices, and techniques of policy development and project management to manage public health projects and resources.
- Ability to communicate information to others regarding public health and program issues.
- Ability to interpret guidelines and agency policies to advise on program operations, including those leading to evaluation and improvement of complex projects and processes.

## 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/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 (FDA) 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 **February 24, 2022** to: [CDER-OC-ODSIR-Recruitment@fda.hhs.gov](mailto: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”. For questions, please contact [CDER-OC-ODSIR-Recruitment@fda.hhs.gov](mailto:CDER-OC-ODSIR-Recruitment@fda.hhs.gov). **Please reference Job Reference ID: T-22-725-D.**

## Announcement Contact

For questions regarding this Cures position, please contact [CDER-OC-ODSIR-Recruitment@fda.hhs.gov](mailto:CDER-OC-ODSIR-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.*

