



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: January 23, 2023 – February 6, 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: Public Health Analyst

Series: AD-0685

Location(s): Silver Spring, MD

Salary: Starting at:
\$78,592 (Band A)

Work Schedule: Full-Time

\$94,199 (Band B)

Cures Band(s): Band A/B

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 compensated 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 are 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.

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.

Duties/Responsibilities

As a **Public Health Analyst**, the incumbent provides public health analytical support to OCQC.

Band A:

- Performs a variety of administrative and operational activities related to major OCQC programs and activities (e.g., related to compounding compliance, quality, regulatory action, enforcement, stakeholder outreach, and policy development related to compounded drugs).
- Adapts existing strategies which allow occupational projects to meet unusual needs or demands and serves as a principal contributor for the assigned specialty areas on team-based projects.
- Works with subject matter experts on projects and assignments, plans and programs for public health initiatives including outreach and metrics related to quality systems and standards. Tracks and reports on project status and program development activities and identify potential adverse impacts and recommends solutions.
- Identifies areas which warrant further study or improvements and prepares reports to ensure optimum operating efficiency and resource utilization.
- Reviews and evaluates public health issues and program operational impact, advises management of potential problem areas, and formulates appropriate responses.

Band B:

- Meets duties and responsibilities outlined in Band A above.
- Serves as a focal point for all levels of FDA personnel providing authoritative guidance and consultation on public health analytical and operational matters related to the human drug compounding program.
- Performs a variety of complex analytical and operational activities related to major OCQC programs and activities (e.g., related to compounding compliance, quality, regulatory action, enforcement, stakeholder outreach and policy development related to compounded drugs).

- Analyzes data and other information to make data driven decisions affecting the operation of OCQC’s programmatic work in support of the public health mission of the agency.
- Provides public health analytical and administrative/operational support to the Office Director, Deputy Directors, and Division Directors in regards to program activities to advance regulatory compliance. Furnishes leadership with critical information for planning, coordination, and evaluation of major OCQC public health program initiatives.
- Identifies areas which warrant further study or improvements and prepares reports to ensure optimum operating efficiency and resource utilization
- Reviews and evaluates complex public health issues and program operational impact, advises management of potential problem areas, and formulates appropriate program responses.

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:

Public Health Analyst, AD-0685 Series

For more information, please see: [OPM Occupational Series Qualification Requirements.](#)

Major study -- public health or other field of study with course work directly related to the work of the position to be filled.

Specialized Experience:Our ideal candidate will possess:

- 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 operationally manage public health or health-related activities.
- 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 Professional Experience:

Our ideal candidate will possess:

Band A

- Ability to apply the Food, Drug and Cosmetic (FD&C) Act, as well as regulations, guidance, and standard operating procedures to public health program operational activities.
- Experience and ability analyzing, evaluating, and making recommendations with respect to operational functions of public health program initiatives and other applicable requirements and policies
- Experience communicating information to others regarding public health and program issues
- Ability to interpret guidelines and agency policies to advise on program operations

- Ability to provide guidance and consultation to achieve public health and program operational objectives

Band B

- Meets duties and responsibilities outlined in Band A above.
- Experience applying the Food, Drug and Cosmetic (FD&C) Act , regulations, guidance, and standard operating procedures to public health program operational activities.
- Experience and ability analyzing, evaluating, and making recommendations with respect to operational functions of public health program initiatives and other applicable requirements and policies.
- Experience communicating information to others regarding public health and program issues.
- Experience and skill in interpreting guidelines and agency policies to advise on program operations.
- Experience and skill in providing guidance and consultation to achieve public health and program operational 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/Moderate Risk (A/B) security clearance.

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 in PDF format by **February 6 , 2023** to: CDER-OC-COMPOUNDING-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”.

Please title the email subject **“OCQC – DCPO – CB6 – Public Health Analyst Band A/B application”** when applying or submitting questions.

Announcement Contact

For questions regarding this Cures position, please contact CDER-OC-COMPOUNDING-RECRUITMENT@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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