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 Manufacturing Quality (OMQ)

Application Period: September 30, 2024 – October 15, 2024

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): Remote Anywhere in the U.S.

Salary: $99,119 – 133,845

Work Schedule: Full-Time

Cures Band(s): Band B

Full Performance Band Level: Band B

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 or Agency) 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 **Public Health Analyst**, the incumbent consults on public health analytical matters related to the program operations of human drugs and Current Good Manufacturing Practices (CGMPs) in the Office of Manufacturing Quality (OMQ). In this capacity, the incumbent assists senior analysts and other OMQ employees in identifying program areas which warrant further study or improvements and draft reports to ensure optimum operating efficiency and resource utilization.

- Analyzes and utilizes incoming public health information from inspections, incidents, adverse events, drug shortages, drug quality information to advance the public health mission of the organization, evaluates the public health impact of OMQ programs, and analyzes this data and other information to make data driven decisions affecting the public health mission of the agency. Identifies areas which warrant further study or improvements and prepares reports to ensure optimum operating efficiency and resource utilization.
- Provides public health analytical support (i.e., communication with external stakeholder groups, data analytics, research and/or special projects related to compliance/enforcement actions) to the Office Director, Deputy Directors, and Division Directors regarding regulatory and compliance operations support. Furnishes leadership with critical information that is received by the agency, Center or office from regulated industry, external stakeholders or the public or the planning, coordination, and evaluation of major OMQ public health program initiatives concerning human drug compliance, drug quality, outreach, regulatory programs, and stakeholder engagement.
- Prepares correspondence and provides insight to other divisions and offices in the Center on procedures and methods for dealing with information related to human drugs. Provides input on office key performance indicator standing reports, either at the request of OMQ management, other Center management or are part of an agency directive or mandate (i.e., Generic Drug User Fee Act- GDUFA or the CDER/ORA Concept of Operations) and efficiently handles ad- hoc requests.

- Participates in meetings with the OMQ leadership and others within the office on problems related to regulatory compliance and program management issues under evaluation. Maintains continuing liaison with other organizations within CDER (i.e., Office of Pharmaceutical Quality, Office of Generic Drugs), the Agency and the regulated industry. Provides necessary support in the coordination, planning, consultations, opinions, and endorsements. Provides logistical support to agency taskforces that have national and international impact.

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.

In order 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:

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

Desired Education: Our ideal candidate will possess a major study in public health or other field of study with course work directly related to the work of the position to be filled.

Desired Professional 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 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.
- Conducting studies and performing other analytical work related to the planning, development, organization, administration, evaluation, and delivery of public health programs.

***Please indicate in your resume where you have 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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive-Moderate Risk

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 the 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 actions.

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 a curriculum vitae and cover letter describing why you are uniquely qualified for this position, including how you possess the desired experience and qualifications identified above by **October 15, 2024** to CDER-OC-OMQ-RECRUITMENT@fda.hhs.gov.

Candidate resumes may be shared with hiring officials within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please include ***“Public Health Analyst- Band B”*** in the subject line of the email.

Announcement Contact

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

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