



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 Pharmaceutical Quality (OPQ)
Office of Program and Regulatory Operations (OPRO)

Application Period: April 15, 2024 – April 26, 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.

Commissioned Corp Officers are eligible to apply. Appropriate for O-6 billet.

Position: Supervisory Regulatory Health Project
Manager

Series: AD- 0696

Location(s): Silver Spring, MD

Salary: Starting at \$139,395

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: Will not be paid.

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 the over the counter (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of Pharmaceutical Quality (OPQ) oversees and coordinates the overall regulation of human pharmaceutical quality within CDER, including submission review, manufacturing facility assessment, and surveillance of the quality of marketed pharmaceutical products.

The Office of Program and Regulatory Operations (OPRO) is accountable for leading and coordinating regulatory review processes, facilitating a quality management system, and maintaining a learning and professional development program in collaboration with review offices within the OPQ. Specifically, OPRO is responsible for managing all processes associated with drug product quality review and facility inspections.

The Division of Regulatory & Business Process Management is responsible for leading and managing all processes associated with drug quality review and facility inspections for all applications throughout the drug product lifecycle through the coordination with all OPQ Offices to monitor and track the progress of all internal and cross-functional OPQ projects to ensure completion on time and conformance to the internal processes and procedures.

Duties/Responsibilities

The **Supervisory Regulatory Health Project Manager** oversees the operations, functions, and activities of the organizational unit as carried out by highly trained professional and technical staff.

- Designs, develops, and implements internal processes to support drug quality assessment, in collaboration with the other OPQ and CDER offices.
- Leads and participates fully in strategic planning activities concerning the Branch program segments for pharmaceutical quality assessment.
- Provides technical oversight and guidance pertaining to specific drug regulatory and quality initiatives.
- Implements initiatives regarding regulatory guidance and project management and provides on the assessment process and procedures.

Supervisory Responsibilities: Manages multiple projects and provides leadership to personnel within the branch. Supervises and evaluates staff who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff performing the work and functions of the organizational unit. Obtains resources, identifies strategic objectives, and establishes goals for the Branch. Executes strategic objectives for the organization.

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 and Experience Requirements:

Consumer Safety Officer, 0696

- A. A 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.

The 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

- B. 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 see: [OPM Occupational Series Qualification Requirements](#).

Desired Professional Experience:

Our ideal candidate will possess:

- Ability to apply knowledge of regulatory assessment process and project management skills.
- Demonstrated managerial experience in a diverse organization.
- Ability to develop networks and build alliances. Experience collaborating cross boundaries to build strategic relations and achieve common goals.
- Ability to identify internal and external politics that impact the work of the organization.
- Ability to identify and analyze problems, weighing relevance and accuracy of information, in order to evaluate alternative solutions and make recommendations.
- Experience in organizational change management.
- Ability to effectively and efficiently communicate with various audiences with varying levels of domain expertise.
- Demonstrated success in implementing information management systems that effectively meet business needs.
- Ability to work independently and as a contributing, productive, 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

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 action.

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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs 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

All qualified candidates should submit their resume and transcripts to OPQOPRORecruitment@fda.hhs.gov no later than **April 26, 2024**.

A resume, not a CV, must be received. You can access the [USA Jobs Resume Builder](#) to assist with building your resume.

If you have foreign transcripts, please submit the foreign transcript course-by-course evaluation from an accredited company ([NACES](#) or [AICE](#)). 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 reference Job Reference ID: **OPRO: Supervisory Regulatory Health Project Manager** in the subject line.

How You Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact OPQOPRORecruitment@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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