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 Pharmaceutical Manufacturing Assessment (OPMA)

Application Period: September 16, 2024 – September 27, 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 an O-5 Billet.

Position: Regulatory Specialist

Series: AD-0696

Location(s): Anywhere in US (Remote)

Salary: $117,962 - $164,260

Work Schedule: Full Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: Up to 50%

Bargaining Unit: 3591

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 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 pharmaceutical quality within CDER, including quality assessment of regulatory submission, manufacturing facility assessment, research, policy development, and surveillance of the quality of marketed pharmaceutical products.

The Offices of Pharmaceutical Manufacturing Assessment (OPMA) serves as the OPQ's centralized resource on manufacturing and facility (including inspection) issues that impact application assessment.

Duties/Responsibilities

As a **Regulatory Specialist**, the incumbent serves as a subject matter expert (SME) for the inspection/investigation of firms engaged in the manufacture, processing, and control of human pharmaceutical and biologics products to evaluate compliance with the requirements of the Food Drug & Cosmetic Act and the Current Good Manufacturing Practice regulations as it pertains the preapproval and pre-license inspection programs.

- Performs a minimum of two domestic inspections and two international inspections per calendar year.
- Plans, conducts, and directs highly technical, complex, and multi-faceted inspections and in-depth investigations of establishments engaged in the manufacture of biologics, biosimilars, and new and generic human pharmaceuticals.
- Reviews and evaluates comprehensive information and data on the manufacturing process and controls, microbiology controls and sterility assurance, as well as technical product quality microbiology aspects of labeling, and the implementation of the relevant manufacturing control strategy at facilities submitted in Investigational New Drugs (INDs), Drug Master Files (DMFs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and supplemental Biologics License Applications (BLAs), NDAs, and ANDAs as appropriate.

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.*

Title 21 Minimal Qualifications:

Education: A bachelor's degree or higher in quality assurance/management, data science, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food science, law or regulations, or related healthcare or science field. The degree must be from an accredited program or institution.

OR
Experience: Comparable regulatory experience or FDA regulated product lifecycle experience focused on enforcing and/or ensuring compliance with FDA laws and regulations or experience in one or more of the following:

- Knowledge of the FD&C Act combined with experience in either Current Good Manufacturing Practices (cGMP), or auditing products that the FDA regulates.
- Interpreting the statute, regulations, guidance, and other quality policies to assess

compliance, quality, manufacturing performance, or quality management maturity.
- Product development, process development, scale-up, or commercial manufacturing.
- Sterility assurance and microbiological controls.

Desired Professional Experience:
Our ideal candidate will possess:

- Ability to independently perform scientific analysis to interpret and evaluate the results of analyses submitted by sponsors/applicants.
- Ability to travel four or more times a year with a minimum of two domestic and two international travels.
- Demonstrated knowledge of and experience with identifying and collecting data, compiling, and analyzing data, and making sound decisions/recommendations in areas where precedents and guidelines are inadequate.
- Ability to apply new developments and theories to critical and novel problems; extend and modify approaches, precedents, and methods to solve a variety of scientific problems with unprecedented and obscure aspects; and make decisions or recommendations that significantly affect the content, interpretation, or development of major policies or programs concerning critical or major scientific issues.
- Knowledge of pharmaceutical manufacturing, microbiology quality and/or technology, associated with drugs for human use obtained through academic training.
- Knowledge of related sciences, such as microbiology, biology, molecular biology, virology, bacteriology, chemistry, physics, engineering, and/or biopharmaceutics to review drug applications or amendments and supplemental applications to interpret statutes, program policies, and procedures; and develop guidelines and provide technical leadership in drug application processing.
- Ability to identify and analyze problems; weigh the relevance and accuracy of information; generate alternative solutions; and make recommendations in a timely manner.
- Ability to communicate and work with staff across the organization and with differing expertise; demonstrated ability to collaborate across boundaries to work toward common goals 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 / 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 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

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

All qualified candidates will submit their cover letter, resume, and transcripts to OPQOPMARecruitment@fda.hhs.gov no later than September 27, 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: **OPMA Regulatory Specialist** 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 OPQOPMARecruitment@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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