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

Application Period: June 23, 2022 – July 7, 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.

Commissioned Corp Officers are eligible to apply.

Position: Regulatory Health Project Manager

Series: AD-0696

Location(s): Silver Spring, MD

Salary: Starting at:
$89,834 (Band B)
$106,823 (Band C)

Work Schedule: Full Time

Cures Band(s): Band B/C

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 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 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). CDER's drug regulatory responsibilities include premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotion activities; review, monitoring, and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

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 OPQ. Specifically, OPRO is responsible for managing all processes associated with drug product quality review and facility inspections.

The Divisions of Regulatory & Business Process Management I, II, and III (DRBPM I, II, III) leads and manages 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

As a **Regulatory Health Project Manager**, the incumbent coordinates/manages the application review process for an assigned group of drug/biological products or office level programs associated with drug quality application review and facility inspections throughout the drug product lifecycle.

Band B:

- Coordinates with the regulatory manager/coordinator for an assigned group of drug/biological products or office level program.
- Serves as primary point-of-contact with regulated industry for all issues related to the status of applications or office level programs.
- Ensures all goals, deadlines, and other metrics specified in the applicable User Fee Act (UFA), laws, statue, regulations, and internal procedures are met for assigned projects.
- Reviews all assigned applications to identify risks that may adversely impact the quality or timeliness of review activities.

Band C:

- Meets duties and responsibilities outlined in Band A and B above.
- Serves as the regulatory manager/coordinator for an assigned group of drug/biological

products or office level programs. Manages (coordination, fact-finding, etc.) applications from investigational stage through marketing application review, and post-marketing quality oversight.
- Establish and implement all goals, deadlines, and other metrics specified in the applicable User Fee Act (UFA), laws, statue, regulations, and internal procedures are met for assigned projects.
- Ensures the overall progress of each application by creating project plans, timelines, and other supporting materials to expedite the communication and completion of review activities by all relevant disciplines.

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:

Consumer Safety Officer, 0696

Degree: 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

Combination of education and experience—courses consisting of at least 30 semester hours in the fields of study described above, plus appropriate experience or additional education.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Education: Our ideal candidate will possess education including chemistry, biological sciences, and other related scientific backgrounds.

Desired Professional Experience:

Our ideal candidate will possess:

- Demonstrated experience in fact finding, investigative techniques, and in applying analytical and evaluative methods and techniques.
- Skill in planning and organizing the work teams to accomplish a variety of concurred activities performed in several organizations and to anticipate subtle and difficult issues.
- Experience working through and with others to achieve desired project results.
- Ability to apply knowledge of project management techniques and concepts to manage large, complex projects with diverse stakeholders.
- Ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative solutions; drafts recommendations.
- Ability to apply knowledge of data gathering methods and analytical/evaluative techniques.
- Skilled in effective/efficient meeting management.

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 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.

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

All qualified candidates should submit their resume with cover letter and unofficial transcripts (if you have foreign transcripts, please submit foreign transcript evaluation from an accredited

company) by **July 7, 2022,** to OPQOPRORecruitment@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". This pool of candidates may be used for future vacant positions through October 30, 2022. For questions, please contact OPQOPROecruitment@fda.hhs.gov.

Announcement Contact

For questions regarding this Cures position, please contact Dominique.Mitchell@fda.hhs.gov.

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