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 Generic Drug (OGD)
Office of Bioequivalence (OB)
Division of Bioequivalence Process Management (DBPM)

Application Period: October 31, 2023 - November 8, 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: Regulatory Health Project Manager

Series: AD-0601/0660/0696

Location(s): Silver Spring, MD

Salary: $112,015-$155,978

Work Schedule: Full-Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: Relocation expenses 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 mission of the Office of Generic Drug (OGD) and its sub offices is to ensure high-quality, affordable generic drugs are available to the American public. OGD is the world leader in the science and regulation of generic drugs serving an essential role in advancing FDA's public health mission.

The mission of the Office of Bioequivalence (OB) is to assist in the evaluation and response to bioequivalence aspects of Abbreviated New Drug Applications (ANDAs), citizens petitions, suitability petitions, controlled correspondences, dispute resolutions, Congressional inquiries, and other regulatory activities related to generic drugs.

The mission of the Division of Bioequivalence Process Management (DBPM) is to lead and manage all processes associated with the bioequivalence review throughout the drug product lifecycle for all Abbreviated New Drug Applications (ANDAs), and act as internal liaison for all bioequivalence-related questions within OGD, as well as offices/centers outside of OGD, who are associated with the ANDA review process.

Duties/Responsibilities

As the **Regulatory Health Project Manager**, the incumbent is responsible for assisting with conducting regulatory science research to establish equivalence standards for generic drugs that will ensure therapeutic equivalence.

- Provides pre-submission scientific advice to Abbreviated New Drug Applications (ANDA) sponsors on equivalence standards for generics drugs including complex products. Ensures the therapeutic equivalence of approved generic drugs through post-approval research and investigation of potential safety or product use issues.
- Serves as a scientific, regulatory, and technical resource providing assessment and evaluation for the generic drug process and program activities within OGD.
- Reviews and assesses the submission requirements of generic drug applications/abbreviated new drug applications, providing recommendations to enhance and improve the critical mission of the Office. Conducts activities to meet Generic Drug User Fee Amendments (GDUFA) goal dates.
- Replies to correspondence from regulated industry and other interested parties and provides counsel as needed in order to inform and educate on policies, application procedures, and other guidance related to the generic drug program. Issues are often regulatory in scope.
- Leverages available methods, technology, and information to produce a quality work product. Prepares written deliverables in collaboration with members that convey relevant information to outside stakeholders.
- Provides input, recommendations, and innovative strategies when collaborating with experts within the Office and across the Abbreviated New Drug Applications (ANDA) program to modify and develop systems, policies, and procedures to address the needs

of the program segments.

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.
- 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:

General Medical and Healthcare, AD-0601 Series

Degree: A bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Pharmacy, AD-0660 Series

Degree: A doctoral degree in Pharmacy that is recognized by the Accreditation Council for Pharmacy Education(external link) (ACPE) or an accrediting body recognized by the U.S. Department of Education(external link) at the time the degree was obtained.

Licensure Requirements: Applicants must be licensed to practice pharmacy in a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

Professional Experience:
Our ideal candidate will possess:

- Demonstrated knowledge, skills, abilities, and competencies necessary to perform the work of the position. Knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties. Qualifying professional pharmacy experience may involve, but is not limited to:
- Ability to dispense medications prescribed by physicians and other health practitioners and providing information to health practitioners and patients about proper usage of medications and side effects.
- Ability to evaluate medication use patterns and outcomes for patients in hospitals or managed care organizations.
- Ability to perform administrative, consultative, or staff advisory work for a medical facility's pharmacy program.
- Ability to plan, monitor, and evaluate medication programs or regimens.
- Ability to establish medication-handling procedures for the storage and preservation of medications.
- Ability to research medical literature and/or clinical medication information to provide accurate responses to inquiries; and/or maintaining all medication records required by law.

Consumer Safety, AD-0696 Series

Applicants must meet one of the following requirements:

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 in paragraph A above, plus appropriate experience or additional education.

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

Professional Experience:
Our ideal candidate will possess:

- Ability to manage a challenging project with several parallel processes from start to finish, with recognition of milestones and challenges to completion. Demonstrated experience with applying project management techniques and concepts to manage large, complex projects with diverse stakeholders.
- Ability to independently identify and analyze problems; weigh relevance and accuracy of information; generate and evaluate alternative solutions; make recommendations and/or implement program changes.
- Experience assessing information/data and making decisions on issues related to complex drug products.

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.

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 or curriculum vitae with cover letter by **November 8, 2023**, to: Lauren.Sams@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions regarding this Cures position, please contact Lauren.Sams@fda.hhs.gov.

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