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)

Application Period: December 19, 2022 – December 30, 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 (appropriate for an O-6 billet).

Position: Branch Chief

Series: AD-1320/0401

Location(s): Silver Spring, MD

Salary: Starting at $126,233

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: 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 Lifecycle Drug Products (OLDP) evaluates and assesses product quality aspects of Abbreviated New Drug Applications (ANDA) and makes risk-informed recommendations on the approvability of such products, evaluates, and assesses post-marketing activities for both the approved brand and generic drug products, and participates in scientific investigations to evaluate and assess drug product quality concerns. The Divisions of Immediate & Modified Release Products I, II, &III (DIMRPI, DIMRPII, DIMRPIII) manages the overall program responsibilities for the division, primarily assessments and establishment of adequacy for the drug product sections of original Abbreviated New Drug Applications (ANDAs).

Duties/Responsibilities

As **Branch Chief**, the incumbent plans and directs branch activities and oversees the scientific review and quality evaluation of immediate and modified release generic drug products assigned to the branch, including related Abbreviated New Drug Applications (ANDAs), and/or supplemental ANDAs, and when appropriate Bio-Investigational New Drugs (INDs) and Drug Master Files (DMFs). The incumbent interacts with branch staff, consisting of 8-12 scientists, throughout the review process to ensure technical alignment and agreement with review decisions and to monitor the lifecycle of both innovator and generic drugs.

- Assign and manage quality assessments for ANDAs, and when appropriate, INDs, ANDAs, DMFs, and/or their supplemental submissions. Provides supervisory concurrence for Branch employee's quality assessment of the immediate and modified release drug products found in these applications in accordance with applicable regulations, guidance/guideline, quality standards, Branch, and Division policy and procedures. Ensures alignment of Branch activities and goals with the strategic plan of the Office.
- Provides input on Division policies in collaboration with the Division Director and the Office of Policy for Pharmaceutical Quality to establish standards for lifecycle drug product review activities, including novel and complex product design and/or manufacturing technologies. Provides expert scientific and regulatory advice and guidance concerning approaches and options that are sound and feasible in relation to Branch goals and conforms to GDUFA programs and regulations governing the application review.
- Serves as the final authority on pre-approvability for all assigned applications

pertaining to INDs, ANDAs, DMFs, and/or associated supplements prior to the primary review office rendering the FDA decision on the applications. Ensures the branch review decisions conform to the negotiated timelines for the applicable drug product.

- Directs the analysis and implementation of new laws and regulations that affect the branch and have the potential to impact changes in FDA guidance, processes, and procedures.

Supervisory Responsibilities: Manages multiple projects and provides leadership to staff of 8-12 personnel. Supervises and evaluates scientists 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. 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 Requirement:

Chemistry, AD-1320 Series

Degree: Physical sciences, life sciences, or engineering that include 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics. Or a combination of education and experience – course work equivalent to a major as shown above, including at least 30 semester hours in chemistry, supplemented by mathematics through differential and integral calculus, and at least 6 semester hours of physics, plus appropriate experience, or additional education.

Biologist, AD-0401 Series:

Degree: Biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. Or a combination of education and experience with courses equivalent to a major as shown above plus appropriate experience or additional education.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Education:

Ideal candidate will possess: Graduate level or higher degree in a technical field from an accredited institution.

Professional Experience:

Our ideal candidate will possess:

- Knowledge of regulatory assessment process and project management skills.
- Demonstrated ability to identify the internal and external politics that impact the work of the organization. Perceives organizational and political reality and acts accordingly.
- Demonstrated ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative decisions; makes recommendations.
- Successful experience in organizational change management.

- Expert ability to communicate, verbally and in writing, and work with staff at all levels of the organization and varying levels of domain expertise; excellent listening skills and a commitment to communicate in a timely manner.
- Ability to work independently and as a contributing and collaborative team member.
- Ability to organize time effectively, determine priorities, and move work forward.

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.

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 a course-by-course foreign evaluation from an accredited company (NACES or AICE) by **December 28, 2022** to OPQOLDPRecruitment@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 reference job ID:** OLDP – Branch Chief.

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 Dominique.Mitchell@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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