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 Quality Research (OPQR)

Application Period: May 6, 2024 – May 17, 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: Pharmaceutical Scientist

Series: AD-0601

Location(s): Silver Spring, MD and Beltsville, MD

Work Schedule: Full Time

Salary:
$82,764 - $109,506 (Band A)
$99,200 - $133,845 (Band B)
$117,962 - $164,260 (Band C)

Cures Band(s): Band A/B/C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

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 Office of Pharmaceutical Quality Research (OPQR) provides key scientific data, analytical tools, and subject matter expertise, which inform regulatory decisions and actions and advance the field of pharmaceutical quality.

Duties/Responsibilities

As the **Pharmaceutical Scientist**, the incumbent serves on a multi-disciplinary scientific team. Provides technical guidance in research activities designed to resolve specific scientific issues to support regulatory assessment, policy development, and decisions.

- Reviews and evaluates a broad range of biopharmaceutical and chemical data which are received as part of the clinical and analytical documents submitted in drug applications.
- Designs the characterization, performance, and bioequivalence of complex drug products (E.g., ophthalmic emulsions, ointments, and suspensions as well as injectable suspensions and liposomes).
- Conducts characterization and bioequivalence assessment of complex drug substances.
- Develops and evaluates models, bioassays, or scientific approaches to support the development of drugs and biological products.

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 pharmaceutical science, pharmaceutical engineering, pharmacology, chemistry, biology, microbiology, chemical engineering, biochemical engineering, pharmacy, biochemistry, molecular biology, physical sciences, life sciences, engineering, mathematics, PharmD, biological sciences, agriculture, natural resource management. The degree must be from an accredited program or institution.

Desired Professional Experience:
Our ideal candidate will possess:

- Ability to apply knowledge of multi-disciplinary product quality guidance standards.
- Experience implementing laboratory or pilot plant research projects related to product quality involving unit operations, measurement systems, and automation. Experience evaluating of vitro characterization studies of product performance.
- Experience in problem-solving techniques, including identifying complex problems, gathering information, drawing conclusions, recommending solutions, providing advice to other scientists, and negotiating acceptance and implementation of recommendations.

- Experience developing research projects to fill gaps in knowledge related to biology, chemistry, microbiology, engineering and/or pharmacology.
- Experience designing, developing, and validating the review protocols to evaluate the pharmacology of regulated compounds such as drugs or chemicals.
- Experience utilizing written communication techniques to generate scientific reports. Experience preparing papers and reports for publication.
- Experience utilizing oral communication techniques to present findings and recommendations utilizing scientific terms.
- Experience interacting, establishing, and maintaining effective relationships with customers, information sources, and multi-disciplinary team members.
- Ability to apply sound judgment regarding their decision and/or evaluation of drugs, chemicals, and toxic agents.
- Experience providing authoritative guidance to scientists in the application of Agency rules, regulations, and procedures.

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

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 will submit their cover letter, resume, and transcripts to OPQOPQRRecruitment@fda.hhs.gov no later than **May 17, 2024. The application period will either close on May 17, 2024, or after the Agency receive 100 resumes (applications)**. Once that number has been reached, the vacancy announcement will close.

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: **OPQR Pharmaceutical Scientist** 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 OPQOPQRRecruitment@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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