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)

Application Period: November 24, 2021 – December 15, 2021

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: Pharmaceutical Scientist

Series: AD-1320/1301/401/896

Location(s): Silver Spring, MD

Salary: Starting at $72,750 and is commensurate with qualifications (CURES Bands A, B, and C)

Work Schedule: Full-Time

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

Full Performance Band Level: Band C

Travel Requirements: 25% or less

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 or Agency) 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 are 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.

Duties/Responsibilities

The Pharmaceutical Scientist is responsible for reviewing and evaluating comprehensive information and data on chemistry, formulation, manufacturing (including process monitoring and controls), biopharmaceutics (including drug release), as well as technical aspects of labeling and environmental impact submitted in Biologic License Agreements (BLAs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and supplemental BLAs, NDAs, as appropriate. The pharmaceutical scientist performs a full range of duties in one or more of the specialized areas described below, primarily monitoring the lifecycle of both innovator or biological products and generic or biosimilar drugs through a team-based evaluation and assessment of supplements and annual reports using risk management practices.

Duties/Responsibilities (Band A):

The incumbent will serve in a developmental capacity to eventually perform the Band C master professional duties. Work assignments are designed to introduce the full range of duties and responsibilities required for the Full Band Advancement (Band C).

- Evaluates the identification and characterization of drug substance's pharmaceutical properties and their impact on the drug products performance, manufacturing, and quality.
- Assess the choice of inactive ingredients (known as excipients) in a drug delivery system including its formulation and product design.
- Applies a risk and scientific-based approach to evaluate the adequacy of formulation studies to understand the impact of drug substance and excipient attributes on drug product performance.

Duties/Responsibilities (Band B):

Duties and responsibilities outlined in Band A above.

- Drafts and recommends patient-centric quality standards for drug product to ensure its clinical performance.
- Evaluates the adequacy of analytical procedures and controls, as well as associated sampling plans for quality testing, monitoring, and control.
- Participates in facility inspections related to the evaluation of manufacturing processes and controls and in support of pre-approval and continuous good manufacturing practices (cGMP) inspections.

Duties/Responsibilities (Band C):
Duties and responsibilities outlined in Bands A and B above.

- Formulates recommendations and decisions in areas where precedents and guidelines are inadequate, utilizing scientific background and understanding of broad legislation, policy statements, and regulatory program definitions.
- Identifies and analyzes the role of the manufacturing process variables affecting pharmaceutical intermediates and finished products for various manufacturing processes through scientific or engineered approaches.
- Evaluates the adequacy of sponsors data and results, including drug substance and drug product manufacturing, in-process, release, and stability data, using appropriate quantitative of mathematical approaches or tools.

Supervisory Responsibilities: None.

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:

Natural Resources Management and Biological Sciences, 401:
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 listed, plus appropriate experience or additional education.

Pharmacy Series, 0660:
A doctoral degree in Pharmacy that is recognized by the Accreditation Council for Pharmacy Education (ACPE) or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Licensure: 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.

Basic Requirements for the GS-11 (or equivalent) Grade Level: 3 years of progressively higher-level graduate education leading to a Ph.D. degree, Ph.D., Pharm.D. or equivalent doctoral degree.

Basic Requirements for the GS-12 (or equivalent) Grade Level: In addition to the requirements for the GS-11 (or equivalent) level, applicants must have a minimum of one year of professional pharmacy experience.

Basic Requirements for the GS-13 and above Grade Levels: In addition to the licensure and education requirements described above, a minimum of one year of professional pharmacy experience that is equivalent to at least the next lower grade level.

Medical Requirements: Applicants must be able to distinguish basic colors.

Note: Employees assigned to positions in this occupational series as of September 2017 will be considered to have met the basic requirements for the position occupied.

Experience: Applicant's qualifications and background must demonstrate the knowledge, skills,

abilities, and competencies necessary to perform the work of the position. Pharmacy work requires 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:

- Dispensing medications prescribed by physicians and other health practitioners and providing information to health practitioners and patients about proper usage of medications and side effects.
- Evaluating medication use patterns and outcomes for patients in hospitals or managed care organizations.
- Performing administrative, consultative, or staff advisory work for a medical facility's pharmacy program.
- Planning, monitoring, and evaluating medication programs or regimens.
- Establishing medication-handling procedures for the storage and preservation of medications.
- Researching medical literature and/or clinical medication information to provide accurate responses to inquiries; and/or
- Maintaining all medication records required by laws.

Chemistry Series, 1320:

Degree: physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours in physics. Or, a combination of education and experience with course work equivalent to a major listed, 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.

General Physical Science Series, 1301

Degree: physical sciences, engineering, or mathematics that included 24 semester hours in physical science and/or related engineering science such as mechanics, dynamics, properties of materials, and electronics. Or, a combination of education and experience with education equivalent to one of the majors listed that included at least 24 semester hours in physical science and/or related engineering science, plus appropriate experience, or additional education.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Education: 3 years of progressively higher-level graduate education leading to a Ph.D. degree, Ph.D., Pharm.D. or equivalent doctoral degree.

Desired Professional Experience:

- Ability to independently perform scientific analyses and testing; interpreting and evaluating the results of analysis; determine whether control strategies (including raw material control, analytical methods, in process control, etc.) are suitable for ensuring

product quality and performance from a regulatory standpoint; and prepare scientific reports documenting the performed analysis with minimal supervisory input.
- 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 formulation and technology associated with drugs for human use obtained through academic training.
- Knowledge of related sciences, such as biology, chemistry, physics, engineering, and/or biopharmaceutics in order to review drug applications or amendments and supplemental applications to interpret statues, program policies, and procedures; and develop guidelines and provide technical leadership in drug application processing.

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 should submit a resume and unofficial transcripts (if you have foreign transcripts please submit a foreign transcript evaluation from an accredited company) by December 15, 2021 to: OPQ_Cures_Recruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact OPQ_Cures_Recruitment@fda.hhs.gov. Please reference Job Reference ID: **OPQ Pharmaceutical Scientist**

Announcement Contact

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

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FDA is an equal opportunity employer.