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 Testing and Research (OTR)

Application Period: June 20, 2023 – June 30, 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.

Commissioned Corp Officers are eligible to apply. Appropriate for an O-5 billet.

Position: Pharmaceutical Scientist (Research)

Series: AD-1320/1301/0403/0401

Location(s): St. Louis, MO

Work Schedule: Full Time

Salary:
$78,592 - $103,964 (Band A)
$94,199 - $127,096 (Band B)
$112,015 - $155,978 (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 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 Testing and Research (OTR) conducts laboratory research on manufacturing, formulation, and characterization of drugs, and provides advice/consults, collaborative research opportunities, and scientific training to FDA staff on pharmaceutical quality, pharmaceutical equivalency, and bioavailability/bioequivalence issues including manufacturing, formulation, analytical testing, and modeling.

Duties/Responsibilities

As a **Research Scientist**, the incumbent serves on multi-disciplinary scientific teams and provides technical guidance in research activities which generally include the characterization of drug products, its formulation and manufacturing process as it relates to drug delivery, in vitro drug release and in vivo drug performance.

- Develops methods for the characterization of 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
- Provides development and optimization of analytical methods and specifications, using various analytical methods, and the development of innovative methods to address quality issues.
- Develops advanced manufacturing approaches for drug substances and drug products including understanding of excipients effects, design of experiments, control strategies, and modeling.
- Reviews and evaluates a broad range of biopharmaceutical and chemical data which are received as part of clinical and analytical documents.
- Serves as the primary author and/or drafts scientific articles within the scientist's area of expertise. Maintains contact with the "state of science" in order to identify and integrate the most advanced research theory and/or practice into the Center's drug regulatory programs.
- Works with scientific teams to resolve pharmaceutical issues related to the safety, efficacy, and quality of regulated drug 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.*

Education Requirement:

Chemistry, AD-1320 Series

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 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.

General Physical Science, AD-1301 Series
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.

Microbiologist, AD-0403 Series
Degree: microbiology; or biology, chemistry, or basic medical science that included at least 20 semester hours in microbiology and other subjects related to the study of microorganisms, and 20 semester hours in the physical and mathematical sciences combining course work in organic chemistry or biochemistry, physics, and college algebra, or their equivalent. Or a Combination of education and experience: Courses equivalent to a major in microbiology, biology, chemistry, or basic medical science, 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: Courses equivalent to a major, plus appropriate experience or additional education.

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

Desired Education:
Our ideal candidate will possess a minimum of 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:
Our ideal candidate will possess:

- Ability to advise scientists in the application of Agency rules, regulations, and procedures.
- Ability to identify problems, gather information, draw conclusions, recommend solutions, and negotiate acceptance and implementation of recommendations.
- Experience developing research projects to fill gaps in knowledge related to drug substances and products.
- Experience designing, developing, and validating the review protocols to evaluate pharmaceutical products and their ingredients.
- Experience evaluating in vitro characterization studies of product performance.

- Ability to apply knowledge of multi-disciplinary product quality guidance documents.
- Experience utilizing written and oral communication techniques required to generate reports for publication and papers, as well as present findings and recommendations utilizing scientific terms.
- Experience interacting, establishing, and maintaining effective relationships with customers, information sources, and team members.
- Ability to apply sound judgment regarding their decision and/or evaluation of drugs, chemicals, and toxic agents.

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.

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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs 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 access a virtual interview platform via HireVue where you will be directed to record answers to screening questions. Recordings to all questions must be complete before the conclusion of the announcement period for application packages to be considered completed. Your recorded answers, cover letter, and resume should be uploaded to your HireVue profile by **June 30, 2023.**

Please send copies of your transcripts to OPQOTRRecruitment@fda.hhs.gov no later than **June**

30, 2023.

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". This pool of candidates may be used to fill vacant positions through August 5, 2023.

Please reference Job Reference ID: **OTR Research Scientist (St. Louis, MO)** 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 OPQOTRRecruitment@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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