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)
Office of Office of Biotechnology Products (OBP)

Application Period: September 29, 2021 – October 13, 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 may apply.

Position: Interdisciplinary Scientist

Series: AD – 1320/405/403/401

Location(s): White Oak, Silver Spring, MD

Salary: Starting at $103,690 (CURES Band C)

Work Schedule: Full Time

Cures Band(s): 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 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 Biotechnology Products (OBP) conducts assessment and research of biological and biosimilar products and supports OPQ in the overall regulation of pharmaceutical quality.

Duties/Responsibilities

- Participates in a research program led by a Principle Investigator in their area of expertise (e.g., chemistry, biology, microbiology, pharmacology or related sub-disciplines). Contributes to the design and interpretation of experiments and results, and their impact on the research program. The research program should be compliant with the mission of the Agency.
- Reviews submissions to determine the technical content of labeling and ensure consistency with the information submitted in the application is in compliance with labeling requirements of the law and regulations.
- Participates in pre-approval and cGMP inspections, as necessary, to better determine approvability and marketability of the drug products. Such determinations are based on quality design and the ability to identify process problems that relate to quality design.
- Provides scientific expertise as a member of multi-disciplinary scientific and medical teams engaged in review, evaluation, and decision-making regarding approvability of submissions and applications requesting FDA regulatory consideration of clinical research, testing and manufacture of human drugs and any other related regulatory submissions.
- Discuss and confirm the need for any additional data or tests from sponsors and applicants, or propose changes to the manufacturing process or manufacturing controls when the researcher/reviewer determines that they are needed to establish and maintain the identity, purity, strength and quality of the drug product.
- Ensures timely and effective communication with the sponsors and timely completion of reviews according to Good Review Management Principles (GRMP) timelines.

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:

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.

Please review the entire Individual Occupational Requirement (IOR) to confirm the minimum education requirements in the following link. Chemist, 1320

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. Biologist, 401

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. Microbiology, 403

Degree: major in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology. Pharmacology, 405

Professional Experience:

To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the level of the position. Qualifying experience involves enforcing laws and regulations to protect consumers from drugs that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.

- Possess a graduate level or higher degree in a technical field from an accredited institution.
- Mastery skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods sufficient to conceive and apply experimental theories and new development applications to extend and modify theories, concepts, and assumptions; resolve unique or novel problems, conditions, and issues; and significantly alter standard practices, equipment, devices, processes, and known techniques.
- Expert knowledge of broad operating programs to advise senior colleagues and agency officials and manages significant projects that represent an important segment of the agency's operating programs.
- Skill in chemistry, biology, microbiology or pharmacology to apply this knowledge set to the review of Investigational New Drugs (INDs), New Drug Applications (NDAs) and Biologic License Applications (BLAs).Successful experience in organizational change management.
- Ability to communicate in writing, orally, and visually to communicate scientific findings, advocate positions, make formal presentations, and convey information

related to a wide range of scientific and regulatory issues.
- Skill in conducting negotiations with representatives of the regulated industry to secure acceptance of recommendations and concurrence with requirements, which may involve changes in established processes or conflict with the industry's objectives.

Desired Professional Experience: Our ideal candidate will possess at least one (1) year of specialized experience overseeing the review of regulatory submissions (i.e. INDs, BLAs, NDAs, Investigational Device Exemptions (IDEs), Premarket Approval (PMAs). At a minimum, this position requires a degree in a scientific field which will give the individual knowledge of biotechnology sciences and experience and ability to perform research to support FDA regulatory decisions and actions on new drug/biologic products; and planning and organizing the work of others or of a team to complete a scientific project.

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: 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 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 resume or curriculum vitae with cover letter and unofficial transcripts (if you have foreign transcripts please submit foreign transcript evaluation from an accredited company) by October 13, 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 Dominique.Mitchell@fda.hhs.gov.. Please reference Job Reference ID: **Interdiciplinary Scientist, OBP**

Announcement Contact

For questions regarding this Cures position, please contact Dominique Mitchell, Supervisory Administrative Officer, via email at Dominique.Mitchell@fda.hhs.gov.

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