Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
U.S. Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Pharmaceutical Quality (OPQ)

Application Period: February 13, 2023 – February 24, 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: Interdisciplinary Scientist

Series: AD-1320/0403/0401

Location(s): Silver Spring, MD

Salary: $112,015 - $155,978

Work Schedule: Full-Time (Telework Eligible)

Cures Band(s): Band 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 and prescription drugs, including biological therapeutics and generic drugs.

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 Policy for Pharmaceutical Quality (OPPQ) develops, implements, and updates science and risk-based policies, standards, guidance documents, and internal policies related to the assessment of drug components and drug products for human use. The Compendial Operations and Standards Staff (COSS) coordinates OPQs participation in external standards organizations with Subject Matter Experts from OPQ, in addition to coordinating the review of proposed changes to existing or the creation of new standards regarding drug components and drug products, including over-the-counter products, and determines if issues require FDA review.

Duties/Responsibilities

As the **Interdisciplinary Scientist**, the incumbent provides advice and consultation to office management on pharmaceutical quality standards related policy matters including scientific area of expertise, and provides analysis and recommendations for effective development of OPQ policy and program strategies in the assessment of quality and/or labeling information submitted in investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) and assessed as part of current good manufacturing practice (CGMP) inspections.

- Leads cross-office standards liaison working groups providing scientific and regulatory technical expertise and knowledge in the biological science, microbiology, or pharmacology area to subject matter experts, facilitating timely and efficient policy decision-making and development of CDER/FDA consensus position and comments regarding difficult issues.

- Conducts assessment of pharmaceutical quality standards and FDA policies in one of the disciplines, including those related to the integrated quality assessment of marketing applications, ongoing surveillance of pharmaceutical product manufacturing facilities.

- Serves as a CDER liaison representative to United States Pharmacopeial Convention (USP) Expert Committees and standards development organizations which develop pharmaceutical quality standards. Coordinates and communicates FDA recommendations and responses to USP and standard development organizations.

- Develops responses to inquiries regarding quality and/or labeling-related topics (e.g., questions regarding application content, CGMP expectations, and interpretation of

published policies) from interested parties external to OPQ, CDER, and the Agency, including controlled correspondence, other pharmaceutical manufacturer inquiries, media inquiries, and citizen petitions, with input from subject matter experts as appropriate. Conducts research or works with experts in CDER labs to guide the development of scientific research to address or support standards and policy issues under consideration.

Supervisory Responsibilities: NA

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 Series, AD-1320

Degree in 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 with coursework equivalent to a major listed 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. Chemistry, 1320

Microbiology Series, AD-0403

Degree in 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 working organic chemistry or biochemistry, physics, and college algebra, or their equivalent. Or a combination of education and experience in courses equivalent to a major in microbiology, biology, chemistry, or basic medical science that included courses shown above, plus experience or additional education. Microbiology, 0403

Biology Series, AD-0401

Degree in biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. Or a combination of education and experience in courses equivalent to a major shown above, plus appropriate experience or additional education. Biology, 0401

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

Professional Experience:

Our ideal candidate will possess:

- Knowledge of regulatory policies, and procedures, related to the regulation of pharmaceutical quality.
- Ability to identify and analyze problems; weigh the relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations.
- Ability to communicate and work with staff at across the organization and with differing expertise.
- Demonstrated ability to collaborate across boundaries to work toward common goals.
- Ability to work independently and as a contributing, collaborative team member.
- Ability to organize time effectively, determine priorities, and move work forward.
- Familiarity with pharmaceutical quality related labeling policies.
- Familiarity with the use of Unites States Pharmacopeia (USP) and voluntary consensus

standards in pharmaceutical quality assessments.

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 by **February 24, 2023** to HireVue, our automated interview system. 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 Job Reference ID: **OPPQ – Interdisciplinary Scientist.**

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 OPQOPPQRecruitment@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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