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)

Application Period: August 26, 2022 – September 9, 2022

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: Associate Director for Science

Series: AD-1301/0401

Location(s): Silver Spring, MD

Salary: Starting at $148,484.00

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: 8888

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) 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 the over the counter (OTC) and

prescription drugs, including biological therapeutics and generic drugs.

The Office of Policy for Pharmaceutical Quality (OPPQ) develops, implements, and updates science and risk-based policies and standards related to human drug product quality, including application assessment and inspection.

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.

Duties/Responsibilities

As an **Associate Director for Science**, incumbent serves as a technical expert and senior advisor to the Deputy and Office Director for the Office of Policy for Pharmaceutical Quality (OPPQ) on matters related to the advancement of policy related to pharmaceutical quality by providing expert scientific experience and extensive knowledge of Federal statutes and regulations. Through the promotion of Good Guidance Practices (GGP) and appropriate policy tools, the incumbent will inform on and provide leadership for the development and implementation of OPQ, CDER, and/or Agency policy, including policy harmonized or agreed upon with international regulators (e.g., through the International Council for Harmonization (ICH)).

- Serves as a point of contact for the office to provide scientific technical input to the content and strategic direction of policy documents under development, evaluation, or revision where additional scientific expertise and oversight are needed.
- Leads development of office specific policies and processes. Applies a comprehensive knowledge of program activities and requirements such as statutes, in order to implement regulations, existing policy, and policy development approaches in providing expert scientific input to OPPQ and OPQ management.
- Develops partnerships, networks, and builds alliances with Offices/Agencies, and other government components (e.g., National Institutes of Health (NIH) and National Institute of Standards and Technology (NIST); drug regulatory agencies (e.g., European Medicines Agency (EMA), Ministry of Health, Labor, and Welfare (MHLW), Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada).
- Negotiates and gains alignment with stakeholders across CDER, to accomplish Center/Agency readiness to perform quality assessments of products, conduct inspections, and establish guidance and standards for the regulated pharmaceutical industry.

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:

General Physical Sciences, 1301:

Degree: physical science, 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

Combination of education and experience with education equivalent to one of the majors previously listed that included at least 24 semester hours in physical science and/or related

engineering science, plus appropriate experience, or additional education.

General Natural Resources Management and Biological Sciences, 401:
Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

Or

Combination of education and experience with courses equivalent to a major previously listed plus appropriate experience or additional education.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Professional Experience:
Our ideal candidate will possess:

- Knowledge of regulatory assessment process and project management skills.
- Ability to conduct scientific or regulatory research in the areas of advanced analytics, biopharmaceutics, manufacturing, or formulation chemistry for pharmaceuticals.
- Ability to identify and analyze problems: weighs relevance and accuracy of information; generates and evaluates alternative decisions; and makes recommendations.
- Ability to work independently as a contributing and collaborative team member, and work with staff at all levels of the organization and varying levels of domain expertise.
- Ability to develop networks and build alliances; collaborating across boundaries to build strategic relationships; building consensus; and achieving common goals.
- Ability to communicate, verbally and in writing; and a commitment to communicate in a timely manner.

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 and unofficial transcripts (if you have foreign transcripts please submit a course-by-course foreign evaluation from an accredited company (NACES or AICE) by **September 9, 2022** to: OPQOPPQRecruitment@fda.hhs.gov. 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". For questions, please contact OPQOPPQRecruitment@fda.hhs.gov. Please reference Job Reference ID: **OPPQ Associate Director for Science.**

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 Dominique Mitchell, Supervisory Administrative Officer, via email at Dominique.Mitchell@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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