



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: April 20, 2023 – May 1, 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: Quality Assurance Specialist

Series: AD-1910

Location(s): Silver Spring, MD

Salary: \$112,015 - \$155,978

Work Schedule: Full Time (Hybrid)

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 (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.

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 the **Quality Assurance Specialist**, the incumbent implements the Quality Management Plan (QMP) or other established guidelines for the OPQ Quality Management System (QMS) for the chemistry, manufacturing, and controls (CMC) review and research and testing laboratory processes.

- Participates in developing, implementing, and maintaining the CMC and laboratory QMS and the QMP, including related documents.
- Identifies opportunities within the OTR to develop and improve the CMC review and research laboratory processes and ensures supporting activities are aligned with quality concepts and goals.
- Develop tentative/final operating criteria and procedures, staff, and operational quality standards and protocols, and any other communications pertaining to the CMC and laboratory QMS.
- Coordinates the resolution of OTR matters related to QMS components, including planning, implementation, and evaluation of process improvement tools utilized.
- Ensures facilities, environment, laboratory, metrological traceability, validation of methods, sampling, calibration, and control of data are consistent with the QMS.

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:

Quality Assurance Series, AD-1910:

Degree: Undergraduate or graduate education in a major study such as quality assurance, statistics, mathematics, production management, industrial management, computer science, engineering, engineering technology, physical sciences, textiles, or the fields related to the position.

For more information, please see: [OPM Occupational Series Qualification Requirements](#).

Desired Education:

Our ideal candidate will possess:

A quality related certification, such as American Society for Quality (ASQ) certification, or the

ability to obtain a quality related certification is desirable.

Desired Professional Experience:

Our ideal candidate will possess:

- Independently exercises a very high degree of skill and aptitude in analyzing and resolving extremely complex improvements related to quality assurance and in the specific application of new and emerging developments and technology in pharmaceutical science.
- Demonstrates expertise in conducting system and process audits, risk management, writing detailed reports and recommendations, facilitating communication, and cultivating positive inter-office and team dynamics.
- Working knowledge of broad and practical levels of regulation including but not limited to FDA laws, regulations, policies, and guidelines pertaining to pharmaceutical science and quality management frameworks from the industrial and regulatory perspective to effectively lead in the development, implementation, and maintenance of the QMS for the CMC review process.
- Experience performing quality assurance programs for pharmaceutical laboratory research and testing operations.

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 qualifications 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 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 **May 1, 2023**.

Please send copies of your transcripts to OPQOTRRecruitment@fda.hhs.gov NLT **May 1, 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 1, 2023.

Please reference Job Reference ID: **OTR Quality Assurance Specialist**.

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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