



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 Generic Drugs (OGD)

Application Period: August 25, 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.

Position: Lead Quality Assurance Specialist

Series: AD-1910

Location(s): Silver Spring, MD

Salary: Starting at \$126,233

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25 % or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: Relocation expenses 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 mission of the Office of Generic Drugs (OGD) is to provide oversight, leadership, strategic direction, and ensure high-quality, affordable generic drugs are available to the American public. Oversees the development and implementation of standards for the safety and effectiveness of generic drugs, the review and assessment activities of Abbreviated New Drug Applications (ANDAs), their amendments and supplements to determine their approvability according to standards consistent with the Food, Drug and Cosmetic (FD&C) Act and relevant sections of the regulations.

The mission of the Quality Management Staff (QMS) is to develop formal business practices for processes and procedures to ensure efficient and consistent OGD work processes and products. Monitors, reviews, and measures OGD performance relative to quality objectives. Formulates and conduct audits to identify non-conformity, gaps, and opportunities for quality improvement. Provide reports to OGD senior management on quality data trends and anomalies to identify opportunities for improvement in work processes and product efficiencies. Facilitates, continually, and participates in process improvements and quality planning activities to ensure OGD delivers high quality products, processes, and services through quality tools such as lean six sigma.

Duties/Responsibilities

As the **Lead Quality Assurance Specialist**, the incumbent serves as a subject matter expert and conducts quantitative and qualitative analyses to ensure efficient and consistent work processes and products across OGD; critiques, designs, installs, and improves management planning systems, organizational development, strategic planning, and survey and decision models. In this capacity, the incumbent advocates for and represents OGD product owners and all OGD staff in the matter of CDER-wide IT development efforts.

- Articulates and communicates to the team the assignment, project, problem to be solved, actionable events, milestones, and/or program issues under review and research priorities, and deadlines and time frames for completion. Leads the team in identifying, distributing, and balancing workload and tasks among employees in accordance with workflow, skill level, and/or occupational specialization.
- Assists Staff Director with the formulation and completion of internal audits to identify non-conformity, gaps, and opportunities for quality improvement within OGD's processes and policies. This includes analyzing quality data to detect unsatisfactory trends or weaknesses in OGD's quality programs.
- Recognizes and defines critical problems, advises Staff Director of alternatives to correct problems identified, and designs methods to implement necessary changes to processes. Explores options, production, and deployment of implementation tools and methodologies to implement necessary changes.
- Identifies strategies to improve the collection and assessment of workload capacity information and applies findings to improve the allocation of regulatory staff and review personnel in assigned review discipline areas throughout OGD and promote new concepts and methods. This includes research related to analyses of productivity, development of profiles of regulated industry and other external stakeholder data

systems as well as form methods for processing of national and State and local data concerning all aspects of career regulatory activities and stakeholder impacts.

- Develops appropriate models to explicitly describe the factors in the problems studied. Provides for weighing constraint factors such as Congressional intent of resource limitation and applies analytical techniques to focus upon practical and regulatory management options.

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 supervisory 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, 1910](#)

Degree: Undergraduate and Graduate Education: Major study -- quality assurance, statistics, mathematics, production management, industrial management, computer science, engineering, engineering technology, physical sciences, textiles, or other fields related to the position.

Meets the Office of Personnel Management (OPM) [OPM Occupational Series Qualification Requirements](#)

Professional Experience:

Our ideal candidate will possess:

- Ability to apply the knowledge, principles, concepts, tools, and methodology related to process quality evaluation, implementation, and strategic analysis.
- Ability to work with facilitating groups with multiple different stakeholders.
- Ability to working independently and as a contributing, collaborative team member when serving as a member of a task force and/or study groups.
- Ability to modulate communication approach depending on audience.
- Ability to constructively interact with a wide variety of stakeholders within the Center, including senior leadership.

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.

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

How to Apply: Submit resume or curriculum vitae with cover letter along with unofficial transcripts by **September 9, 2022**, to: Lauren.Sams@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions regarding this Cures position, please contact Lauren.Sams@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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