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 Drug (OGD)
Quality Management Staff (QMS)

Application Period: October 26, 2023 - November 3, 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.

Position: Staff Director

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $155,700

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: 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Generic Drug (OGD) and its sub offices is to ensure high-quality, affordable generic drugs are available to the American public. OGD is the world leader in the science and regulation of generic drugs serving an essential role in advancing FDA's public health mission.

The mission of the Quality Management Staff (QMS), located in the immediate office, Office of Generic Drugs (OGD), includes but is not limited to the management of Standard Operating Procedures (SOP) related to workflow improvements and training. QMS develops formal business practices for processes and procedures to ensure efficient and consistent OGD work processes and products. Facilitates, continually, and participates in process improvements and quality planning activities to ensure OGD delivers high quality products, processes, and services through quality tools.

Duties/Responsibilities

As the **Staff Director**, the incumbent is responsible for managing a staff of multidisciplinary experts overseeing the planning, execution, monitoring and improvement of systems, projects, and processes as they relate to the generic drug review process and other program operations. Develops and executes the knowledge management (KM) program for the Office of Generic Drugs, which entails the full span of knowledge management efforts with a particular focus on the implementation of innovative platforms and ideas to support the scientific and regulatory processes.

- Serves as the principal advisor for knowledge/information management, the incumbent ensures knowledge management strategies and technologies are embedded in the organization's processes.
- Works with OGD executive leadership to understand Office needs, resources, and data available and utilize knowledge management initiatives to support the OGD's impact on ensuring high-quality, affordable generic drugs are available to the public.
- Advises on recommended generic drug review programs and projects that will support the advancement of state of the art scientific and regulatory informatics and knowledge management, applying best practices and approaches.
- Directs organization leadership on knowledge management principles, concepts and application into the generic drug program's processes and procedures that includes the development of an integrated management framework that harnesses information through innovation. Identifies and influences key information technology infrastructure approaches to enable knowledge management, including leveraging available databases and migrating them to sustainable enterprise platforms.
- Leads the implementation of knowledge management concepts and ensures full integration into core business procedures through incorporation of enterprise IT platforms and readily available and accessible tools and techniques into the organizations regulatory decision-making process.
- Develops and participates in process and quality improvement projects aimed at

identifying improvements and efficiencies in the generic drugs review program of the organization.

Supervisory Responsibilities: Manages Quality Management Staff providing leadership and management oversight to subordinate staff performing the work and functions of the organizational unit. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time. Obtains resources and identifies strategic objectives for the organization.

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 Medical and Healthcare, AD-0601 Series

Degree: A bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

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

Professional Experience:
Our ideal candidate will possess:

- Successful experience with overseeing knowledge management standards of an organization.
- Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.
- Demonstrated ability to identify and analyze problems; weigh relevance and accuracy of information; generate and evaluate alternative solutions; make recommendations.
- Ability to communicate and work with staff at all levels of the organization and varying levels of domain expertise; excellent listening skills and a commitment to communicate in a timely manner.
- Ability to work independently and as a contributing, collaborative team member.
- Ability to organize time effectively, determine priorities, and move work forward.

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.

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

Submit resume or curriculum vitae with cover letter by **November 3, 2023,** to: Lauren.Sams@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CDER 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.

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