Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Human Foods Program (HFP)/Office of Quality Assessment and Management
Supervisory Quality Assurance
Office Director

Application Period: 09/03/2024 – 10/02/2024

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: Office Director (Supervisory Quality Assurance)

Series:

1910, Quality Assurance

Title 21 Band(s):

Band G

Full Performance Band Level: Band G

Location(s): College Park, MD

Work Schedule: Full Time

Salary: Starting at $213,491

Travel Requirements: Up to 25%

Bargaining Unit: 8888, Non-bargaining Unit

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 is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Human Foods Program (HFP) is to protect and promote the health and wellness of all people through science-based approaches to prevent foodborne illness, reduce diet-related chronic disease, and ensure chemicals in food are safe.

Duties/Responsibilities

The Office of Quality Assessment and Management (OQAM) leads the quality initiative for the Human Foods Program (HFP), supporting a culture of continuous improvement and optimization of program operations. The Office is responsible for evaluating and making fitness-for-use determinations of food safety systems and also making recommendations to HFP leadership on maximizing domestic and international regulatory partners' food safety work to increase public health protection. OQAM also assesses and monitors the efficacy and efficiency of HFP programs and procedures and makes recommendations to HFP leadership of options for improvement. The Office Director manages the Quality Assessment Staff and Quality Management Staff and performs the following:

- Provides executive-level management, leadership, and consultation on HFP's quality management system and assessments program; ensures that quality standards and audits and assessments following consistent practices.
- Creates and implements quality assessment and management practices, policies, and procedures to align with the organization's goals and objectives.
- Leads the formulation of audit activities and programs. Ensures that inspection, investigation, sample collection and analysis, enforcement, response recovery and outreach components meet programmatic standards.
- Serves as principal advisor to the Deputy Commissioner, HFP leadership, and Agency leadership on all matters concerning quality management and assessment programs, standards, and policies. Serves as an expert advisor on ISO accreditation requirements and activities.
- Leads innovative approaches on leveraging external (state/international) food safety systems to inform risk prioritization in collaboration with other HFP offices.
- Leads the collaboration with other HFP offices and the development of training for HFP staff to ensure that quality standards are integrated into all aspects of the organization.
- Assesses current internal processes and procedures to identify inefficiencies and opportunities for improvement. Oversee the implementation of process improvements

based on assessment findings, ensuring changes enhance quality and performance. Identify potential risks related to quality and develop mitigation strategies to minimize their impact.

- Keeps abreast of industry trends, standards, and best practices to ensure that the organization's QA practices remain current and effective.
- Establishes and maintains liaisons throughout HFP, within FDA and Department of Health and Human Services (HHS), State, local, and international regulatory partners, and key representatives from agencies and programs for which the office conducts business to inform and explain regulations and audit procedures and processes.
- Participates in and contributes to top level HFP, Agency, and Department discussions, meetings, and conferences on matters and issues concerning HFP's quality management system and assessments program. Monitors, coordinates, and advises the Deputy Commissioner, HFP leadership, and staff on new and revised policies.
- Ensures that the organizational structure of the Office provides for uniformity, optimum effectiveness, and operational efficiency. Analyzes and defines significant obstacles to program accomplishments and recommends changes and initiates action to ensure effective resource utilization and the elimination of unnecessary duplication. Promotes and encourages intra- and inter-program cooperation to achieve program objectives.
- Manages the personnel and financial resources of the Office ensuring that resources are allocated and utilized in accordance with the identified priorities and core functions of the HFP.

Supervisory Responsibilities:
Supervisor provides occupational specific technical and administrative direction 25 percent or more of the time to three or more subordinate employees performing the work and functions of the organization. * Obtains resources and identifies strategic objectives for the organization. * Defines jobs, selects employees, and assigns work; defines technical work requirements and milestones; evaluates the organization and employee accomplishments by accepting or rejecting work products; and presents and defends organization and employees work to senior management and other offices. * Recommends employee promotions and recognition; approves leave; implements performance modifications and takes corrective actions as appropriate. * Provides equal opportunity in all Federal human capital and employment programs regardless of race, color, gender, national origin, religion, age, disability, genetic information, sexual orientation, affiliation or non-affiliation with a labor organization, political affiliation, status as a parent. * Provides employees resources and information that insures a safe and healthy work environment.

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.

In order 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 Required:

Education

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; OR

Specialized Experience (for positions above GS-5): Experience that demonstrated a practical knowledge in monitoring, controlling, or maintaining the quality of products or

services in quality assurance, procurement, inspection, production, or related areas. Examples include:

- Reviewing production activities and capabilities in light of contract quality requirements.
- Reviewing written quality or inspection procedures for adequacy, and evaluating the implementation and effectiveness of quality/inspection systems, including sampling plans.
- Analyzing quality data to detect unsatisfactory trends or weaknesses in the quality/inspection system.
- Verifying by test or inspection, using sampling inspection or intensive product inspection techniques, that products comply with requirements prior to acceptance.
- Identifying inadequacies and requesting corrective action.
- Computing data, summarizing results, and preparing reports or charts depicting pertinent relationships using statistical methods.
- Investigating customer complaints and deficiency reports, and providing identification of causes to appropriate authorities.
- Reading, interpreting, and applying technical data such as blueprints, engineering drawings, product specifications, or technical manuals.
- Reviewing and evaluating supply systems operations and procedures through periodic audits and surveillance inspections.

Desired Professional Experience or Education:

- At least 5 years of experience leading teams or work related to quality management and assurance with demonstrated success in building a quality culture focused on driving continuous improvement within an complex organization.
- Familiarity with a variety of technology solutions, such as automation and artificial intelligence, that support the optimization and improvement of program operations.
- Demonstrated ability to analyze business processes and procedures, identify root causes, generate corrective/preventive actions, and oversee and evaluate the process improvement effort.
- Experience communicating highly technical information in a clear way and working with staff at all levels of the organization and varying levels of domain expertise.
- Demonstrated ability developing networks and building alliances with internal and external parties; collaborating across boundaries to build strategic relationships and achieve common goals.

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-Critical Sensitive – High Risk

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. 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.

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.

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 and a copy of all transcripts (with foreign credential evaluation, if applicable) by the closing date as identified above to hfpexecutiveresources@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CFSAN with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions please contact hfpexecutiveresources@fda.hhs.gov. Please reference Job Reference ID: OQAM, Office Director.

Announcement Contact

For questions regarding this Cures position, please contact hfpexecutiveresources@fda.hhs.gov. Please reference Job Reference ID: OQAM, Office Director.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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