Title 21 Cures Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Operations (ORO)
Immediate Office of the Director (IOD)

Application Period: May 15, 2024 – May 29, 2024
Initial cut-off period for first-referral consideration is May 22, 2024 at 11:59 p.m. (ET); applications received after this date will be given consideration only if there is a need for further applicant review, until a selection is made or on the closing date of May 29, 2024.
Area of Consideration: The Public
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: Health Scientist (Quality System Regulatory Review)

Series: 0601

Work Schedule: Full Time

Salary Range: $139,395 – $191,900 and is set commensurate with education and experience.

Telework Eligible: Yes – as determined by agency policy

Location: Remote Eligible position

Title 21 Band: D

Full Performance Band Level: D

Travel Requirements: 25% or less

Bargaining Unit: 3591

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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 or Agency) 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 Center for Biologics Evaluation and Research (CBER) is a Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. CBER protects and advances the public health by ensuring that biological products are safe, effective, and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

The Office of Regulatory Operations (ORO) is responsible for managing the review process and associated activities used to support CBER in facilitating the regulation and review of biological products, drugs, devices, and combination products. These responsibilities include development and governance of regulatory business processes; data standards; regulatory data analysis; program evaluation; resource utilization; user fee management; electronic submission management; and special initiatives. ORO manages CBER's Information Technology investments throughout their lifecycle to support and ensure CBER's review, scientific, and administrative needs are met.

Duties/Responsibilities

The incumbent serves as the Health Scientist (Quality System Regulatory Review) under the Office of Regulatory Operations (ORO). The incumbent develops, administers and advises on work concerned with assuring the quality of work transactions, business processes, and delivery of services needed to carry out CBER's programs and functions that significantly affect the quality of regulatory work products and activities. The incumbent is a recognized expert and authority for quality system analysis of programs, operations and processes, including document control, knowledge management, risk analysis, strategic planning, project management, continuous process improvement, and corrective/preventive action for CBER's managed review process.

Specifically, the Health Scientist (Quality System Regulatory Review) will:

- Develop, implement and manage an integrated, CBER-wide, quality management system for regulatory review process activities and be responsible for formulating, determining, and influencing the policies that impact the managed review process and regulatory work products CBER-wide.
- Establish annual and multi-year strategic goals, priorities, and objectives for the Quality System which align and support CBER, FDA, and HHS organizational and agency level strategic plans.
- Lead the development and implementation of program goals and objectives to determine and evaluate the sequence and timing of key program events and milestones and methods of evaluating the outcome measures of program accomplishments.
- Ensure that quality provisions are planned, developed and implemented to identify, prevent, correct and improve unsatisfactory conditions and elements which influence the regulatory accuracy and responsiveness of transactions and services.
- Advise the ORO Director/Associate Director for Review Management, CBER Director, CBER senior leadership, and other stakeholders on the development of strategies for applying quality management to regulatory review program areas, significant quality improvement needs and corrective actions, and other aspects of the quality program for regulatory review.
- Coordinate and develop quality system training for all Center staff involved in regulatory revew process.

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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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 Requirement:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Position's Desired Skills, Experience, or Education:

- Demonstrated experience in developing, implementing and managing a quality management systems and programs.
- Mastery of quality management tools and expertise in accordance to the ASQ American Society for Quality (ASQ). Certification as a Manager of Quality/Operational Excellence CMQ/OE desired.
- Mastery of numerous qualitative and/or quantitative methods for the assessment and improvement of program effectiveness or the improvement of complex management processes and systems.
- Mastery of statistical techniques and basic quality tools to analyze quality data, facilitate root cause analysis and investigations and manage the implementation of process improvements as well as corrective and preventive actions.
- Demonstrated experience in solving complex management problems and administering these solutions.
- Familarity with laws, regulations, and guidance pertaining to regulation drugs, biologics, or devices and their regulatory review process.
- Experience in conducting timely analysis and writing comprehensive reports.
- Experience negotiating to consolidate positions and to resolve differing points of view.

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: 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.

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

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

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

Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), SF50 (if applicable), latest PMAP (if applicable), copy of unofficial transcript (s) and letter of interest with ***"Title 21 Vacancy Announcement CBER/ORO Health Scientist (Quality System Regulatory Review) "*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through May 29, 2024.

Announcement Contact

For questions regarding this Cures position, please contact CBERHumanCapital@fda.hhs.gov.

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

FDA is an equal opportunity employer.