Title 21 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)
Division of Regulatory Operations and Programs (DROP)
Regulatory Programs Branch (RPB)

Application Period: November 3, 2023 – November 17, 2023

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: Regulatory Specialist
*Multiple selections can be made

Series: 0696

Location(s): Remote Eligible position

Salary: Starting at $112,015

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band: Band C

Full Performance Band Level: Band C

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 (IT) investments throughout their lifecycle to support and ensure CBER's review, scientific, and administrative needs are met.

The Division of Regulatory Operations and Programs (DROP) oversees CBER's Managed Review Process (MRP) and governance of regulatory operations. These responsibilities include the review of policies and procedures; review-related committees; interaction with offices on review and regulatory issues to facilitate application of statutes, regulations, guidance, and processes. DROP provides strategic oversight of review of regulatory submissions at CBER.

The Regulatory Programs Branch (RPB) is responsible for policy formulation, process engineering/re-engineering, and implementation of all Center-level review policies, procedures, review tools, and regulatory templates for use by CBER device reviewers in the Managed Review Process (MRP). These responsibilities include managing the User Fee billing policy and procedures, application assessment, waivers evaluation and processing; tracking the implementation of user fees, legislative and other assigned initiatives within CBER; managing CBER regulatory pediatric programs including Pediatric Research Equity Act (PREA) and Pediatric Review Committee; policies and procedures development; interactions for Combination Products; review vouchers and exclusivity assessments.

Duties/Responsibilities

The Regulatory Specialist (Device)works directly with staff and management to guide the regulatory review process, provide justified recommendations and solutions to all relevant issues that may arise. Regulatory Specialist (Device)develops, recommends, and implements Center operational, science, regulatory review, and/or compliance policies and procedures for medical devices designed to insure consistency and balance throughout the Center. The Regulatory Specialist (Device)identifies and assesses emerging, standing, complex, or precedent-setting issues impacting on Center (science, regulatory review, and/or compliance) operational procedures, policies, activities, and resources.

The Regulatory Specialist (Device)assists staff and management in meeting Agency priorities on work products, addresses all relevant issues, represents credible Center courses of action or response, and ensures input has been secured from all appropriate organizations. The Regulatory Specialist (Device)keeps management apprised on the contents of medical device work products, including controversial issues and of the need for further work.

Specifically, the Regulatory Specialist (Device)will:

- Work on the development of Standard Operating Policy and Procedures (SOPPs), Job Aids, Training, Templates, and Resources to support CBER's Managed Review Process (MRP) of medical devices.
- Oversee staff in guiding, coordinating, and controlling the overall science, regulatory review, and/or compliance workload and work product of the Center.
- Assist staff with evaluating scientific evidence of FDA-regulated products in assessing their safety, effectiveness, and quality; assessing inspection and other data related to manufacturing facilities and practices pertaining to medical device
- Identify and asses the identifying data, documentation, and other evidence needed to support medical device compliance or surveillance activities
- Recommend and implement medical device regulations and guidance on the conduct or participation in inspections and investigations of medical device establishments that design, make, process, hold, or distribute FDA-regulated products to ensure compliance with U.S. laws and regulations
- Assist staff and management with providing specialized counsel, guidance, policy and regulatory interpretation to support programs across the product lifecycle of FDA-medical device regulated products
- Work with appropriate officials in identifying and agreeing upon Center positions and decisions pertaining to medical devices.
- Study background of medical device assigned projects, research appropriate sources of information, and expeditiously recommends a course of action or solutions to appropriately address violative products or circumstances
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- Assists management with providing internal and external stakeholder outreach, assistance, and education of medical devices
- Develop briefing papers providing the probable consequences of the various courses of action along with recommendations, these assignments can include interrelationships with such audiences as other Agency components, other Federal, State, and local agencies, the regulated industry, academia, and health professionals.

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.
- 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 below Education/Graduate Training Requirements 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/Experience Requirements:

0696 Series (Regulatory Specialist)

Education: A bachelor's degree or higher in quality assurance/management, data science, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food science, law or regulations, or related healthcare or science field. The degree must be from an accredited program or institution.

OR

Experience: Comparable regulatory experience or FDA-regulated product lifecycle experience focused on enforcing and/or ensuring compliance with FDA laws and regulations or experience in one or more of the following:

• Knowledge of the FD&C Act combined with experience in either Current Good Manufacturing Practices (cGMP), or auditing products that the FDA regulates.
• Interpreting the statute, regulations, guidance, and other quality policies to assess compliance, quality, manufacturing performance, or quality management maturity.
• Product development, process development, scale-up, or commercial manufacturing.
• Sterility assurance and microbiological controls.

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.

Desired Professional Experience:

- Experience in device regulatory review or project management of medical devices.
- Familiarity with laws, regulations, and guidance pertaining to regulation of medical devices.
- Demonstrated experience in development, evaluation, and implementation of legislation, regulations, and guidance for medical devices.
- Experience in the direct development and implementation of operational tools and procedures, preparing written documents (e.g., Standard Operating Procedures, Job Aids, Templates, etc.) including training staff for regulatory review.
- Experience in regulatory process engineering, writing operational requirements, developing regulatory process models, and metrics development.
- Experience identifying and proposing solutions to critical problems and the need to develop new regulatory approaches or methods that impact medical device operating programs.
- Ability to plan, organize, and carry out assignments; resolve technical conflicts; coordinate with others; and apply established policy and guidelines to achieve objectives.
- Experience managing regulatory, scientific, or technical projects or programs.
- Experience in conducting timely analysis and writing comprehensive reports.
- Knowledge of project management tools (e.g., OneNote, Teams, JIRA) and collaborative workspaces, such as SharePoint Online.
  Knowledge of Microsoft Office Applications (e.g., Excel, Word, Power Point) and Adobe Acrobat.

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), copy of unofficial transcript(s), SF50 (if applicable), latest PMAP (if applicable), and letter of interest with ***"CURES CBER/ORO/DROP/RPB Regulatory Specialist"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **November 17, 2023**.

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.