Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Communication and Education (OCE)
Division of Industry and Consumer Education (DICE)

Application Period: March 19, 2024, through April 16, 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: Branch Chief Premarket Programs

Series: Consumer Safety Officer (0696)

Location(s): Remote Eligible

Salary: Salary is commensurate with education and experience and starts at $139,995.00

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: This position requires up to 25% of travel

Supervisory: Yes

Bargaining Unit: 8888

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 mission of the Center for Devices and Radiological Health (CDRH or Center) is to protect and promote the public health by performing essential public health tasks by making sure that medical

devices and radiological health products are safe for people in the United States. The Office of Communications and Education (OCE or Office) manages communication regarding medical devices and radiation-emitting products to external audiences, education for regulated industry, and communication and training for CDRH employees. The Division of Industry and Consumer Education (DICE or Division) responds to inquiries from the medical device industry and consumers of medical devices and radiation-emitting electronic products. In addition, DICE develops educational resources for the FDA website to help the medical device industry understand FDA regulations and policies.

Duties/Responsibilities

Reporting directly to the DICE Division Director, you will serve as the Branch Chief of Premarket Programs responsible for identifying, developing, establishing, and implementing educational strategic plans that provide public stakeholders with information about FDA's regulatory oversight of medical devices and radiation-emitting electronic products; providing oversight over the completion of staff responses to public stakeholder inquiries about medical devices and radiation-emitting electronic products; and leading the completion of educational programs and products about FDA's regulation of medical devices and radiation-emitting electronic products. Additionally, the Branch Chief for Premarket Programs will perform the following duties:

- Plans, coordinates, and evaluates the programs of the Branch.
- Provides overarching strategic leadership to identify, develop, establish, and implement educational strategic plans that advance stakeholder information about FDA regulatory oversight of medical devices and radiation-emitting electronic products.
- Applies the educational strategic plans to identify, prioritize plan, and assign the specific educational programs and products to be completed by the Branch.
- Develops written and verbal communication skills for staff, so they may educate public stakeholders with understandable and accessible science-based regulatory information about medical devices and radiation-emitting electronic products, and with work that is of high quality, is timely, is accurate, and provides good exceptional customer service.
- Responsible for maintaining the accuracy and quality of educational programs and products developed. This may involve the periodic audit and assessment and may be based on established educational strategic plans or feedback.
- The incumbent leads the assessment of changes to Agency laws, regulations, guidances, and policies to determine impact on existing functions, programs, and activities of the Branch and to identify educational program gaps and public stakeholder needs.

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: Applicants must meet one of the following requirements.

A. A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

   The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

   OR

B. Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

For more information please see: OPM Occupational Series Qualification Requirements

Professional Experience: To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which is equivalent to the following:

- Substantial knowledge and expertise in applying pertinent laws, regulations, policies, precedents, and program goals and objects in the broad field of medical devices, including applying new information

Desired Professional Experience:

- Demonstrated leadership over complex projects, programs, teams, or individuals.
- Experience in delivering regulatory education.
- Experience in preparing regulatory correspondence, including memorandums.
- Excellent leadership and communication skills.
- Ability to build and work effectively within teams.

How to Apply

Submit resume or curriculum vitae, with cover letter and a sample of a regulatory education product or regulatory correspondence. by April 16, 2024 to CDRHRecruitment@fda.hhs.gov. Compile all applicant documents into one combined document (i.e., Adobe PDF). Candidate resumes may be

shared with hiring official within the CDRH with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share." Please include the following Job Reference ID in the subject line of your email submission: **OCE/DICE/Branch Chief of Premarket Programs**

PHS Commissioned Corps Officers interested in performing the duties of this position within the Commissioned Corps may apply to this announcement. Officers must follow the instructions for how to apply and include their most recent orders in addition to the required documents. If selected, candidates will be referred to (CC) personnel and not as candidates for a Cures appointment.

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.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: This position requires a ***Public Trust*** security clearance.

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.

Announcement Contact

For questions regarding this Cures position, please contact CDRHRecruitment@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.