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 Clinical Evidence and Analysis (OCEA)
Division of Clinical Evidence and Analysis III (DCEA3)

Application Period: October 17, 2023, through November 14, 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: Assistant Director

Series: Biologist (401), Microbiologist (0403), Consumer Safety Officer (0696), General Engineer (0801), Materials Engineer (0806), Electrical Engineer (0850), Biomedical Engineer (0858)

Location(s): Remote Eligible

Salary: Salary is commensurate with education and experience and starts at $132,368.00

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: This position may require up to 25% 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

Version: 11/2021

Introduction

The U.S. 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 Product Evaluation and Quality (OPEQ) assures patients have access to high quality, safe, and effective medical devices and products throughout the total product lifecycle (TPLC) by implementing program areas through which medical devices are evaluated or cleared for clinical investigations and marketing. The Office of Clinical Evidence and Analysis' (OCEA or Office) Division of Clinical Science and Outreach (DCEA3) is responsible for epidemiological and real-world evidence infrastructure development, epidemiologic study design, methodology, and data analysis, as well as outreach and collaboration with external stakeholders including hospitals and clinical researchers.

Duties/Responsibilities

Reporting directly to the DCEA3 Deputy Division Director, the Assistant Director provides technical leadership and exercises expert scientific in the regulatory review of data associated with the medical devices and products regulated by the Center. Specifically, the Assistant Director will also performs the following duties:

- Direct and oversee the quality of scientific and regulatory reviews across the total product lifecycle for products assigned to the Division, including premarket evaluation, postmarket evaluation, compliance, and surveillance.
- Develop and implement policies and plans that are sound and feasible in relation to OCEA, OPEQ and Center goals and federal budgetary and economic realities.
- Provide data infrastructure, management and analysis for clinical and real-world evidence, and build relationships and conduct outreach with healthcare facilities.
- Serve as the signature authority on complex work products, as needed on behalf of the Deputy and Division Director of DCEA3.
- Provide guidance and offer feedback to staff on medical device and product reviews, to include those with radiation emoitting properties in the psot-market and surveillance space.
- Provide technical and non-technical support to product advisory panels, panel members, and consultants and acvitivites related to classification actions, petitions, premarket notifications (510(k)s), premarket approval applications (PMAs), PDPs, De Novos, 513(g)s, and Investigational Device Exemptions (IDEs), among other premarket, postmarket, and compliance programs, with Center and Agency components or other organizations, when appropriate.

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:

In order to qualify for this position as a Biologist (0401), Microbiologist (0403), Consumer Safety Officer (0696), General Engineer (0801), Materials Engineer (0806), Electrical Engineer (0850), or as a Biomedical Engineer (0858), applicants must possess the required individual occupational requirements for the series. 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

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:

- Experience in leading and managing interdisciplinary scientists, clinicians, and other regulatory professionals in science-based organizations.
- Experience in interpreting and presenting complex scientific, medical, clinical, and regulatory information and concepts, in both written and oral formats for a variety of audiences.
- Prior experience in a scientific, regulatory, medical device manufacturing, or clinical setting.
- Ability to work collaboratively with a diverse cadre of colleagues and stakeholders in a continuous quality improvement ecosystem.
- Experience in leading the strategic achievement of organizational goals, evaluating organizational performance, and taking action to improve outcomes.

Desired Professional Experience:

- Excellent leadership and communication skills.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.
- Ability to effectiveky communicate through memoranda, position papers, and presentations to senior leaders and other clinical, engineering, technical, and scientific experts.

How to Apply

Submit resume or curriculum vitae with cover letter by **November 14, 2023,** 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: **OCEA/DCEA3/OPT**

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.
- 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.

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.