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 Product Evaluation and Quality (OPEQ)
Office of Clinical Evidence and Analysis (OCEA)
Division of Clinical Evidence and Analysis III (DCEA3)

Application Period: September 14, 2023, through October 12, 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: Deputy Division Director

Series: General Health Science 0601

Location(s): Remote Eligible

Salary: Salary is commensurate with education and experience and starts at $155,700.00

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: This position requires 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

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. As the Deputy Division Director, the incumbent serves under the direction of the DCEA3 Director, regarding matters of general policy, program objectives and priorities, project resource allocations, and budget limitations.

Duties/Responsibilities

As a Deputy Division Director of OCEA/DCEA3, the selected candidate will support the DCEA 3 Director by:

- Directing the design, development, coordination, implementation, and management of complex public health epidemiological studies and surveillance systems to ensure programmatic and project goals and objectives are consistent, compatible, and complementary with mission of the Office and Center.
- Directing and measuring the effects and quality of all aspects of activities under FDA's national Medical Product Safety Network, MedSun, and incorporate the clinical community's perspective into the regulatory and patient-safety work of FDA.
- Drafting recommendations, most of which will be technical in nature, to describe real-world evidence activities, analysis, results, and conclusions to assist in regulatory decision-making.
- Coordinating and collaborating with stakeholders on the development of infrastructure novel methodology for generating real-world evidence.
- Directing the epidemiologic analysis and interpretation for real-world studies.
- Ensuring the safety of marketed devices through overseeing the development of methods for post-market surveillance and conduct of real-world evidence based post-market safety studies.
- Communicating data findings to Office leadership and stakeholders using different visual formats and graphic displays to share meaningful presentations of data and provide reports.
- Forging mutually beneficial formal partnerships with medical device manufacturers, foreign agencies, professional scientific organizations, health care community, patient advocacy groups, academia, and other federal, state, and local stakeholders.
- Creating and sustaining a strong and dynamic culture within the Division including organizational agility, a focus on continuous improvement, and staff empowerment and collaboration.
- Providing subject matter expertise and regulatory support in the form of consultation in the reviews of new medical devices and accompanying test data and reports.

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. OPM Occupational Series Qualification Requirements

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

- Experience in leading and managing interdisciplinary scientists, clinicians, and other regulatory professionals in large-scale science-based organizations.
- Ability to analyze and interpret regulatory policy and guidance to share expertise and advise leadership on highly complex and precedent setting public health matters.
- Leading the strategic achievement of organizational goals, evaluating organizational performance, and taking action to improve outcomes.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Skillful in effectively interpreting and presenting complex scientific, technical, and regulatory information and concepts, in both written and oral formats, for a variety of audiences.

Desired Professional Experience:

- Applicants with advanced degrees in Biomedical Engineering, General Engineering, Systems Engineering, Epidemiology, Data Science, Computer Science, Mathematics, Mathematical Statistics, Statistics, or related fields.
- Prior experience in a scientific, regulatory, or medical device manufacturing setting.

How to Apply

Submit resume or curriculum vitae, transcripts with cover letter by October 12, 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: **DCEA3 Deputy Division Director**

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.

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.

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/ Moderate Risk security clearance.

A background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

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: 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.

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.