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 Health Technology VII (OHT7)
Division of Microbiology Devices (DMD)

Application Period: Tuesday, December 26, 2023 through Friday, January 19, 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: Deputy Division Director

Series: Biologist (0401); Microbiologist (0403); Epidemiologist (0601); General Health Scientist (0601); Physician (0602); Regulatory Specialist (0696); Chemist (1320)

Location(s): Remote Eligible position

Work Schedule: Full Time

Salary: Salary is commensurate with education and experience and starts at $155,700.

Cures Band(s): Band E

Full Performance Band Level: Band E

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

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 CDRH 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. OPEQ assures patients have access to high quality, safe and effective products throughout the total product lifecycle by implementing program areas through which medical devices are evaluated or cleared for clinical investigations and marketing. OHT7 is responsible for the total product lifecycle (TPLC) activities for in vitro diagnostics.

Meet one of the faces behind CDRH here.

Duties/Responsibilities

Reporting directly to the DMD Division Director, you will serve as the senior advisor and primary contact regarding microbiological medical device clinical issues. You will serve as a senior technical advisor to the Office Director, Super Office Director, and other OPEQ and CDRH leadership. Also, the incumbent provides senior advice and leadership to a scientific, clinical, professional, and technical staff throughout the Office. The Deputy Division Director is a nationally and internationally recognized expert with a specialty emphasis on premarket and post market surveillance regulations and policies for in vitro diagnostics devices.

The Deputy Division Director also performs the following duties:

- Serve as the clinical authority on programs and policies concerning premarket review activities, post-market surveillance and quality for in vitro diagnostic medical devices.
- Provide an authoritative analysis and support for all aspects of the Clinical Laboratory Improvement Amendments (CLIA) Program.
- Serves as a subject matter expert/consultant on a variety of technical issues related to the mission of CDRH; develop advance medical device review methods and implement procedures to ensure medical devices are safe and effective.
- May serve as the Acting Division Director when the Division Director is unavailable.

Supervisory Responsibilities: The incumbent operates under the broad supervision of the Division Director and both directs and coordinates DMD administrative management functions relative to the staff supervised, including performance appraisals, professional development plans, training and other personnel issues. The incumbent plays a role in leading the review team, which is comprised of internal and external investigators with a broad range of educational levels and an equally broad range of experience. The incumbent collaborates extensively and deals directly with scientific experts and represents the Division and Center in these contacts in the Director's absence.

The Deputy Division Director also supervises, directs, and coordinates the work of scientific, clinical and technical subject matter experts engaged in the regulatory review of medical devices and establishes and pursues DMD activities that support mission objectives. The Deputy Division Director plans work to be accomplished by subordinates, sets and adjusts short-term priorities, and prepares schedules for completion of work; assigns work to subordinates based on priorities, selective consideration of the difficulty and requirements of assignments, and the

capabilities of employees; evaluates work performance of subordinates; gives advice, counsel, or instruction to employees on both work and administrative matters. Interviews candidates for positions in the Division; recommends appointment, promotion or reassignment of such positions; hears and resolves complaints from employees, referring group grievances and more serious unresolved complaints to a higher-level supervisor or manager; effects minor disciplinary measures, such as warnings and reprimands, recommending other action in more serious cases; identifies developmental and training needs of employees; providing or arranging for needed development and training, finds way to improve productivity or increase the quality of work directed; develops performance standards.

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:

- Biology (0401)
    - **Degree:** biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

OR

    - *Combination* of education and experience: Courses equivalent to a major, as shown in A above, plus appropriate experience or additional education.
- Microbiology (0403)
    - A bachelor's degree or higher in biology, microbiology, or virology. The degree must be from an accredited program or institution.
- Epidemiology (0601)
    - A bachelor's degree or higher in epidemiology, medical, economics, statistics, pharmacology, or public health. The degree must be from an accredited program or institution.
- General Health Scientist (0601)
    - Bachelor's or graduate/higher level degree: major study in an academic field

related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the Unted States Department of Education at the time the degree was obtained.

- Physician (0602)
  - **Education:** A degree from an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

AND

  - **Graduate Training:** In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

- Regulatory Specialist (0696)
  - **Education:** A bachelor's degree or higher in quality assurance/management, data sciences, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food sciences, law or regulations, or related healthcare or science field. The degree must be frm 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 productsthat 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 or microbiological controls.
- Chemistry (1320)
  - A bachelor's degree or higher in chemistry, biochemistry, or molecular/cellular biology. The degree must be from an accredited program or institution.

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:

- Expert knowledge of premarket and surveillance regulations and policies for in vitro diagnostic device assignments (e.g., for IDEs, 510(k)s, PMAs, EIRs, MDRs) and post-market compliance and quality determinations (e.g., Establishment Inspection Report, Regulatory Audit Reports, Recalls, Allegations of Regulatory Misconduct, Labeling, Enforcement Actions, etc.), which is relied upon to make recommendations and decisions that impact public health.
- Knowledge of clinical trial design principles and applications related to infectious disease in vitro-diagnostic devices.
- Ability to effectively manage large and small groups of clinicians and interdisciplinary scientists so that key objectives are met on an appropriate timeline and conflicts are resolved.
- In-depth knowledge in the variety of products for which the Division is responsible, as well as expertise, leadership, and judgment abilities to develop innovative concepts to respond to discoveries impacting the safety of in-vitro diagnostic devices.
- Ability to collaborate across the Agency and engage with external stakeholders to develop and implement consistent policies for public health.

Desired Professional Experience:

Our ideal candidate will possess:

- Excellent leadership and communication skills.
- Ability to work collaboratively with a diverse cadre of customers and stakeholders.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.

How to Apply

How to Apply: Submit resume or curriculum vitae, transcripts with cover letter by ***Friday, January 19, 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: ***Deputy Division Director, OHT7/DMD (Title 21)***

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.

Educational 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.

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 Lindsey M. Nedd at lindsey.nedd@fda.hhs.gov.

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