



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 Strategic Partnerships and Technology Innovation (OST)
Office of Equity & Innovative Development (OEID)
Division of Health Equity (DHE)

Application Period: March 13, 2024 - April 12, 2024

Area of Consideration: FDA-wide

Position: Division Director, Division of Health Equity (DHE)

Series: Biologist (0401), Microbiologist (0403), Chemist (1320), Physician (0602), Epidemiologist (0601), General Engineer (0801), Materials Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858)

Location(s): Remote Eligible position

Salary: Salary is commensurate with education and experience and starts at \$181,551.

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F
Supervisory: Yes

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 the Center for Devices and Radiological Health ([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. The Office of Strategic Partnerships and Technology Innovation ([OSTI](#)) provides leadership for all scientific collaborative and emerging technology related activities at the Center for Devices and Radiological Health (CDRH). The Office of Equity and Innovative Development ([OEID](#)) provides leadership and strategic direction in health equity, patient science, and innovation activities at CDRH. The Division of Health Equity (DHE) provides leadership and strategic oversight for the Health of Women Program, Pediatrics & Special Populations Program, and Innovation Program.

Meet one of the faces behind CDRH [here](#).

Duties/Responsibilities

Reporting directly to the OEID Deputy Office Director, you will provide strategic leadership for the Division of Health Equity and direction to a multidisciplinary workforce engaged in the execution of nationwide programs for the health of women, pediatrics and special populations, and innovation. These programs explore unique issues related to the performance of medical devices in women, pediatrics, the elderly, other special populations, and all underrepresented and underserved populations, in the areas of regulatory research, clinical trials, and the regulatory processes that help assure safe and effective medical devices for all populations. You will provide a vision that aligns with CDRH's public health mission and vision. You will provide leadership in the development of projects and initiatives and advise the OEID Office Director and OEID Deputy Office Director on issues involving development, data strategy, and how they can enable the center's business processes to function most efficiently. The Director of the Division of Health Equity leads organizational changes to continue to improve operational efficiencies and provides improved services for the Center.

The Division Director also performs the following duties:

- Leads, coordinates, communicates, integrates and is accountable for the overall success of the Division, ensuring alignment with critical agency priorities. The Division Director is responsible for ensuring the work efforts achieve the outcome specified within the agency's business strategy. Works on project selections, prioritization, evaluation and monitoring, cost schedule management, risk management, quality management and resource allocations.
- Manages teams that collaborate in fostering the development of medical devices to respond to unmet public health needs and to address challenges of bringing innovative medical devices to market that are safe, effective, and of high quality.
- Manages teams that explore unique issues related to the performance of medical devices in women, pediatrics, the elderly, other special populations, and all underrepresented and underserved populations, in the areas of regulatory research, clinical trials, and the regulatory processes that help assure safe and effective medical devices for all populations.

- Manages all aspects of data, and analytic initiatives as tasked, including large projects and programs from inception/concept through delivery.
- Leads program meetings with a cross functional team to communicate the status of various project activities, discuss issues/risks, and understand the impact of any changes to business requirements.

Supervisory Responsibilities:

The Division Director is responsible for management of policy, priorities, and oversight, and budget resources within the organization. Directs, plans, and assigns and prioritizes work for a division of professional employees based on the nature and difficulty of projects and provides guidance on both work assignments and administrative matters. S/he determines necessary skillsets and training needs. S/he identifies opportunities for growth and professional development opportunities for Division staff within the organization.

S/he develops performance standards, evaluates work performance of subordinates, develops performance appraisals, recommends awards, bonuses, and promotion or reassignment of subordinate staff. S/he approves and disapproves leave, identifies, formulates, and arranges developmental and training needed for staff. This also includes ensuring employees are scheduled and complete initial and yearly safety training and comply with all applicable federal, state, safety and health regulations and established FDA's safety policies and procedures. S/he conducts interviews and selects staff for the division, hears and resolves employee grievances, complaints, and carries out minor disciplinary measures, such as warnings and reprimands, recommending other action in more serious cases.

The Division Director leads the overall project or program when needed. Leads programs in a transparent and productive way, applying standard project management practices. S/he develops the program's key objectives, scope, success criteria, and communicate them effectively across the project team. S/he manages program issues and risks. Communicates program expectations to team and stakeholders in a timely and clear fashion.

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 Office of Strategic Partnership and Technology Innovation (OST) will use the basic requirements defined in the [Office of Personnel Management 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

This position may be filled in the following series:

Physician (0602) 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.

Microbiologist (0403) A bachelor’s degree or higher in biology, microbiology, or virology. The degree must be from an accredited program or institution.

General Health Scientist/Epidemiologist (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.

Chemist (1320) A bachelor’s degree or higher in chemistry, biochemistry, or molecular/cellular biology. The degree must be from an accredited program or institution.

Biologist (0401)

General Engineer (0801), Material Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858) A. Degree: Engineering. To be acceptable, the program must: (1) lead to a bachelor’s degree in a school of engineering with at least one program accredited by ABET; or (2) include differential and integral calculus and courses (more advanced than first-year physics and chemistry) in five of the following seven areas of engineering science or physics: (a) statics, dynamics; (b) strength of materials (stress-strain relationships); (c) fluid mechanics, hydraulics; (d) thermodynamics; (e) electrical fields and circuits; (f) nature and properties of materials (relating particle and aggregate structure to properties); and (g) any other comparable area of fundamental engineering science or physics, such as optics, heat transfer, soil mechanics, or electronics. **OR** B. Combination of education and experience -- college-level education, training, and/or technical experience that furnished (1) a thorough knowledge of the physical and mathematical sciences underlying engineering, and (2) a good understanding, both theoretical and practical, of the engineering sciences and techniques and their applications to one of the branches of engineering.

Desired Education:

Our ideal candidate will possess a doctorate level degree, MD, DO, PharD, PhD.

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

- Managing a multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with food, drugs and/or devices;
- Developing and evaluating policy/guidance and determining appropriate approaches regarding the regulation of food, drugs, and/or devices; and
- Leading the strategic achievement of organizational goals, evaluating organizational performance and taking action to improve performance.

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, cover letter by 3/18/2024 to CDRH-Title-21-Recruitment@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: **CDRH/OST/OEID/DHE 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.

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* 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 Mariela Mercedes at mariela.mercedes@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.

