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)
Immediate Office (IO)

Application Period: Friday, September 15, 2023 through Thursday, September 28, 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: TPLC Fellowship Program Supervisor

Series: Biologist (0401), General Health Scientist (0601), Nurse Consultant (0610), Clinical Laboratory Science (0644), Public Health Specialist (0685), Consumer Safety Officer (0696), General Engineer (0801), Mechanical Engineer (0830), Electrical Engineer (0850), Electronics Engineer (0855), Biomedical Engineer (0858), Chemical Engineer (0893), Physicist (1310), Chemist (1320)

Location(s): Remote Eligible position

Supervisory: Yes

Work Schedule: Full Time

Salary: Salary is commensurate with education and experience and starts at $132,368.

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: This position may require 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. IO (Immediate Office) assures implementation of CDRH and Agency strategic priorities through operational support, strategy, and oversight to the eight Offices of Health Technology (OHT 1-8), Office of Regulatory Programs (ORP), and Office of Clinical Evidence (OCE). This includes the following groups: Compliance and Quality (CQ), Professional Development (PD), Communications, Post-Market Programs (PMP), OPEQ Digital Health (ODH), Clinical and Scientific Policy Staff (CSPS), Quality and Analytics Staff (QAS), Strategic Initiatives Staff (SIS), Regulation, Policy and Guidance Staff (RPGS), and Operations Staff (OS).

Meet one of the faces behind CDRH here.

Duties/Responsibilities

Reporting directly to the Super Office Associate Director for Professional Development, you will serve as the supervisor for the Total Product Life Cycle (TPLC) Fellowship Program. As the supervisor serve as a senior advisor to the Super Office Associate Director for Professional Development, Super Office Director, and other OPEQ and CDRH leadership. Also, the incumbent provides senior regulatory advice and leadership on matters related to total product lifecycle training programs to include programmatic updates, current and future plans, and trends relevant to fellowship program goals and objectives.

The TPLC Fellowship Program Supervisor also performs the following duties:

- Provides expert leadership, scientific and technical guidance, and direction in the oversight of a multidisciplinary team of scientific, regulatory, and professional staff engaged in the TPLC Program.
- Provide advice and scientific guidance to TPLC Fellows in regulatory review practices, agency rules, applicable FDA laws, regulations, policies, procedures, and guidelines.
- Serve as the subject matter expert (SME) to the OPEQ Associate Director for Professional Development Staff and OPEQ Super Office leadership on matters related to TPLC fellowship scientific programs.
- Lead the design, implementation, and evaluation of TPLC fellowship components and scientific program enhancements to ensure reviewers receive pre-market, post-market, compliance, and professional development learning opportunities during the program.

Supervisory Responsibilities: Manage multiple projects and provides leadership, supervision and direction to the team. Plan and prioritize work based on shifting demands at a moment's notice. Gain employee buy-in and support for various clinical evaluations of medical devices and programs. Oversee the quality of scientific, compliance, and regulatory work products and programs within the specific program area.

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:

- Biologist 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.
- Epidemiology/General Health Scientist 0601
    - **Degree**: 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 U.S. Department of Education at the time the degree was obtained.
- Nurse Consultant 0610
    - Although this position does not involve direct patient care duties, candidates must possess the required occupational requirements to qualify. Please use the following link to determine the series qualifications: Nurse Consultant 0610
- Clinical Laboratory Scientist 0644
    - **Degree**: A Bachelor's or graduate/higher level degree from a regionally

accredited college/university including courses in biological science, chemistry and mathematics, AND successful completion of a Medical Laboratory Scientist/Clinical Laboratory Scientist program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained

or

- **A full 4-year course of study** that included 12 months in a college or hospital-based medical technology program or medical technology school approved by a recognized accrediting organization. The professional medical technology curriculum may have consisted of a 1-year post- bachelor's certificate program or the last 1 or 2 years of a 4-year program of study culminating in a bachelor's in medical technology.

Or

- A Bachelor's or graduate/higher level degree from an accredited college/university, including 16 semester hours (24 quarter hours) of biological science (with one semester in microbiology), 16 semester hours (24 quarter hours) of chemistry (with one semester in organic or biochemistry), one semester (one quarter) of mathematics, **AND** five years of full time acceptable clinical laboratory experience in Blood Banking, Chemistry, Hematology, microbiology, Immunology and Urinalysis/Body Fluids. This combination of education and experience must have provided knowledge of the theories, principles, and practices of medical technology equivalent to that provided by the full 4-year course of study described in A or B above. All science and mathematics courses must have been acceptable for credit toward meeting the requirements for a science major at an accredited college or university. Acceptable experience is responsible professional or technician experience in a hospital laboratory, health agency, industrial medical laboratory, or pharmaceutical house; or teaching, test development, or medical research program experience that provided an understanding of the methods and techniques applied in performing professional clinical laboratory work. Certification/licensure as a medical technologist (generalist) obtained through written examination by a nationally recognized credentialing agency or State licensing body is a good indication that the quality of experience is acceptable.

- Public Health Specialist 0685
  - Knowledge of organizational, operational, and programmatic concepts and practices applied by public, private, or nonprofit agencies and organizations engaged in public health or other health-related activities.
  - Knowledge of the methods, processes, and techniques used to develop and deliver public health or health-related programs in State and local settings.
  - Knowledge of a specialized public health program.
  - Knowledge of, and skill in, the application of administrative or analytical methods and techniques necessary for working within the framework of a public

health or related organization and carrying out specific program functions.
    - Skill in oral and written communications, gathering and conveying information, making oral presentations, and preparing reports, correspondence, and other written materials.

- Consumer Safety Officer 0696
    - **Degree**: 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

    - 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.
        - *EXPERIENCE*: To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the grade level of the position. Qualifying experience involves enforcing laws and regulations to protect consumers from foods, drugs, cosmetics, fabrics, toys, equipment, and household products that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.

- All Professional Engineering Positions 0800 (General Engineer 0801, Materials Engineer 0806, Mechanical Engineer 0830, Eletrical Engineer 0850, Biomedical Engineer 0858, Chemical Engineer 0893)
    - **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; € 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

- 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. The adequacy of such background must be demonstrated by one of the following:
  - *Professional registration or licensure*-- Current registration as an Engineer Intern (EI), Engineer in Training (EIT), or licensure as a Professional Engineer (PE) by any State, the District of Columbia, Guam, or Puerto Rico. Absent other means of qualifying under this standard, those applicants who achieved such registration by means other than written test (e.g., State grandfather or eminence provisions) are eligible only for positions that are within or closely related to the specialty field of their registration. For example, an applicant who attains registration through a State Bo'rd's eminence provision as a manufacturing engineer typically would be rated eligible only for manufacturing engineering positions.
  - *Written Test*-- Evidence of having successfully passed the Fundamentals of Engineering (FE) examination or any other written test required for professional registration by an engineering licensure board in the various States, the District of Columbia, Guam, and Puerto Rico.
  - *Specified academic course* -- Successful completion of at least 60 semester hours of courses in the physical, mathematical, and engineering sciences and that included the courses specified in the basic requirements under paragraph A. The courses must be fully acceptable toward meeting the requirements of an engineering program as described in paragraph A.
  - *Related curriculum*-- Successful completion of a curriculum leading to a bache'or's degree in an appropriate scientific field, e.g., engineering technology, physics, chemistry, architecture, computer science, mathematics, hydrology, or geology, may be accepted in lieu of a bachelor's degree in engineering, provided the applicant has had at least 1 year of professional engineering experience acquired under professional engineering supervision and guidance. Ordinarily there should be either an established plan of intensive training to develop professional engineering competence, or several years of prior professional engineering-type experience, e.g., in interdisciplinary positions. (The above examples of related curricula are not allinclusive.)

- Physicist 1310
  - **Degree**: physics; or related degree that included at least 24 semester hours in physics.

or

  - Combination of education and experien– -- courses equivalent to a major in

physics totaling at least 24 semester hours, plus appropriate experience or additional education.

- Chemist 1320
    - **Degree**: physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics.

or

    - Combination of education and experien– -- course work equivalent to a major as shown in A above, including at least 30 semester hours in chemistry, supplemented by mathematics through differential and integral calculus, and at least 6 semester hours of physics, plus appropriate experience or additional education.

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:

- Expertise in total product life cycle medical device reviews with expertise and a mastery of the theories, principles, and methods in a scientific discipline and associated scientific disciplines sufficient to allow the review or regulatory review of a variety of complex industry applications (pre-market, post-market, quality, and compliance).
- Expertise in the review and application of new scientific and technological developments to novel and critical problems which cannot be solved using convential methods, while maintaining knowledge of the recent develops in associated scientific discipline.
- Proven track record in the development and recommendation of solutions to improve and revise scientific programs

Desired Professional Experience:

Our ideal candidate will possess:

- Broad and extensive supervisory experience.
- Ability to perform a variety of TPLC medical device reviews
- 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 **Thursday, September 28, 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: ***TPLC Fellowship Supervisor – Last Name, First Name***

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.

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FDA is an equal opportunity employer.