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 3 (OHT3)

Position: Assistant Director-Injection Devices Team (DHT3C)

Application Period: 7/24/2023 – 8/30/2023

Location(s): Silver Spring, MD

Salary: Starts at $132,368 and is commensurate with qualifications and experience.

CURES Band(s): Bands D

Area of Consideration: U.S. Citizens

Travel Requirements: Up to 25%

Work Schedule: Full Time

Bargaining Unit: 3591

Special Notes: *This position is being filled under an excepted 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 the authority. Additional information on 21st Century Cures Act can be found here.*

Introduction

The Center for Devices and Radiological Health (CDRH), a major regulatory component of the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS), is inviting applications for ***Assistant Director-Injection Devices Team (DHT3C)*** in the Office of Product Evaluation and Quality (OPEQ), Office of Health Technology 3 (OHT3) is responsible for the development of policy related to CDRH's oversight and regulation of clinical trials and other sources of clinical evidence for medical devices. This includes development and implementation of policies related to human subject protection, good clinical practice, and appropriate collection of real-world evidence (RWE).

The Assistant Director for Injection Devices reports directly to the OHT3/DHT3C Division Director and will serve as the technical expert in policies and regulations that impact the activities of OHT3 by providing scientific and technical leadership and expertise in policies and procedures with an emphasis on testing, evaluation, and quality control procedures.

Duties/Responsibilities

The ***Assistant Director-Injection Devices Team (DHT3C)*** duties include, but are not limited to the following:

- Serve as the technical expert in policies and regulations that impact the activities of OHT3, including those relevant to drug delivery combination products. Provides scientific and technical leadership and expertise in policies and procedures, with emphasis on testing, evaluation, and quality control procedures.

- Provide evaluations to the Division Director and other Senior CDRH managers to ensure that OHT3 remains focused on appropriate regulatory science implementation and is in compliance with policy.
- Interact with multiple relevant device, drug, and biologic review groups and teams as designated by the Director. In this way the incumbent helps maintain consistent scientific and/or engineering and regulatory review policies that are consistent with the regulatory science mission and MDUFA policies.
- Formulate consistent scientific and/or engineering review processes through guidance and other mechanisms to ensure that OHT3 is promoting a consistent and transparent regulatory and scientific framework that is consistent with MDUFA and least burdensome policies.
- Review and evaluates Office activities in terms of achieving program goals and objectives and accomplishing assigned functional responsibilities.

Supervisory Responsibilities: Manages multiple projects and provides supervision and leadership to a team of multi-disciplinary personnel. Assigns work, manages timelines, and provides team-level feedback and concurrence on premarket, post-market and compliance submissions. Manages resources by considering employee expertise and workload in task assignment. Assesses progress on reviews, provides guidance on regulatory and scientific issues, and advises on training and professional development. 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. Coach and mentor staff and help sustain a strong and dynamic culture across teams in the Division, including organizational agility, staff empowerment and mobility, and collaboration.

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.*

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

- Managing and/or leading diverse multidisciplinary staff responsible for scientific, technical,

regulatory, and/or public health activities associated with FDA regulated medical devices.

- Leading the strategic achievement of organizational goals and deploying effective interventions to improve organizational outcomes.
- Developing, evaluating, and/or enforcing policies, protocols, guidance documents, and/or recommendations that speak to the safety, efficacy, and reliability of medical products.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.

Desirable Qualifications/Experience:

- Excellent leadership and communication skills (previous supervisory experience preferred).
- Ability to effectively interpret and present complex information and concepts, in both written and oral formats.
- Ability to actively embrace diversity by actively promoting an inclusive workplace that maximizes the talents of each person.
- Ability to focus on objectives and results when considering the various alternatives to a decision.
- Ability to prioritize and make critical decisions in a timely manner.
- Skill in developing and recommending approaches for the resolution of complex situations or those that are sensitive and controversial in nature, using FDA policies, procedures and regulations (e.g. the Federal Food, Drug and Cosmetic Act).
- Interest in the development and implementation of policies and procedures related to medical devices and combination products.

How to Apply

Prior to applying, please see the following instructions:

- Submit an electronic resume or curriculum vitae, a cover letter containing a brief summary of accomplishments and why you're interested in this position.
- Include Job Reference code ***"Assistant Director-INJDT (DHT3C)"*** in the email subject line.
- Email applicant package to CDRHRecruitment@fda.hhs.gov.
- **Visit CDRH Jobs to see additional opportunities.**

Conditions of Employment

- United States Citizenship is required.
- One-year supervisory probationary period may be required.
- Background and/or Security investigation required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption.

Public Health Services Commissioned Corps Officers

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.

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 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 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.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.
FDA is an equal opportunity employer.