



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 4 (OHT4)
Division of Health Technology 4A (DHT4A)

Position: Assistant Director (DHT4A)

Application Period: 4/13/2023 – 5/12/2023

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% or less

Work Schedule: Full Time

Bargaining Unit: 8888

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 a **Assistant Director (DHT4A)** in the Office of Product Evaluation and Quality ([OPEQ](#)), Office of Health Technology 4 ([OHT4](#)), Division of Health Technology 4A ([DHT4A](#)), the Cancer Diagnosis & Treatment Devices Team. DHT4S is responsible for the total lifecycle (TPLC) review of general surgery devices. Reporting directly to the Division Director, you will be responsible for providing expert scientific and regulatory guidance and leadership, growing and managing high-performing multidisciplinary teams, and exercising sound evidence-based judgement and decision-making in the review medical devices and products within the Office's portfolio. Additionally, you will assist and provide the necessary support to advance the strategic vision and initiatives of the Division and Office.

Duties/Responsibilities

The **Assistant Director (DHT4A)** duties include, but are not limited to the following:

- Utilize expert scientific and technical knowledge and vast regulatory expertise to serve as authoritative advisors to Division and Office leadership regarding general surgical, plastics and reconstructive, dermatologic, and/ or infection control medical devices and products, both novel and existing, encompassing the total product lifecycle.
- Collaborate with team members, colleagues, and Division leadership to ensure the uniformed adoption, implementation, and consistent application of OPEQ, OHT 4, and Division-wide guidance, initiatives, and policies regarding regulatory oversight of in-scope

medical devices and products.

- Provide expert consultation to Division and Office leadership on programmatic plans, health care community, scientific, and industry related trends, significant concerns, patient reported outcomes, and adverse event reported data regarding medical devices and products regulated by the Office.
- Provides regulatory oversight and direction for reviews and decisions on classifications, petitions, 510(k)s, HDEs, PMAs, PDPs, IDEs, De Novos and 513(g)s and Investigational Device Exemptions (IDEs) with Office, OPEQ, Center, and Agency components or other organizations, when appropriate.
- Partner with Division, Office, and OPEQ leadership, as appropriate, to leverage the necessary expertise on pre-market, compliance, and surveillance, as well as clinical, scientific, and regulatory policy expertise for reviews.
- Draft decisions and recommendations of public health significance, which may impact the availability of certain products due to safety, efficacy, and reliability concerns.

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 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, evaluating workforce performance, and deploying effective interventions to improve organizational outcomes.
- Enforcing policies, protocols, guidance documents, and/or recommendations that speak to the safety, efficacy, and reliability of medical products.
- 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).

Desirable Qualifications/Experience:

- Skillful in effectively interpreting and presenting complex information and concepts, in both written and oral formats.

- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Ability to actively embrace diversity by 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.

Basic Qualifications: Candidates must possess the required individual occupational requirements to qualify for the following occupational series: [Biologist \(0401\)](#), [Microbiologist \(0403\)](#), [General Engineer \(0801\)](#), [Materials Engineer \(0806\)](#), [Bioengineering and Biomedical Engineering \(0858\)](#), [Chemist \(1320\)](#).

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-IDS (DHT4A)**" 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.