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)
Division of Health Technology 3C (DHT3C)

Position(s): ASSISTANT DIRECTOR, Infusion Devices

Series: The position may be filled by candidates from the following occupational series: Biologist (0401), Microbiologist (0403), General Health Sciences (0601), Physician (0602), Consumer Safety (0696), General Engineer (0801), Materials Engineering (0806), Biomedical Engineer (0858), Electrical Engineering (0850), Physics (1310), and Chemistry (1320)

Location(s): Silver Spring, Maryland, FDA headquarters, White Oak Campus

Travel Requirements: This position may require up to 25% travel.

Application Period: May 19, 2022 – June 20, 2022

Salary: Salary is commensurate with education and experience and starts at $126,233

Conditions of Employment: United States Citizenship is required

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 or Center) assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

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.

Meet one of the faces behind CDRH here.

Position Summary:

Reporting directly to the Division Director, The Assistant Director for the Infusion Devices team provides technical leadership and exercises scientific and engineering judgment in regulating various medical products, primarily drug infusion devices. The Assistant Director oversees the consistent application of policy, regulatory guidance, analysis, interpretation, and programmatic support provided by teams within the Division to other parts of the Office, Office of Product Evaluation & Quality (OPEQ), and CDRH to ensure timely, accurate, and high-quality work products. Also, the Incumbent oversees the quality of scientific and regulatory reviews across the total product lifecycle for products assigned to the Division, including premarket evaluation, postmarket evaluation, compliance, and surveillance. As a technical and scientific expert on products within the Division management team, provides guidance and feedback to staff on product reviews and other medical or radiological health product-specific activities and programs.

Duties/Responsibilities:
The Assistant Director also performs the following duties:

- Shares with the Division Director the responsibilities for the management of all activities within the Office.
- Works with Division management team to ensure appropriate staffing for review of files within the Division
- Serves as a technical and scientific expert on products within the division management team for the purpose of providing technical guidance and feedback to team staff on product reviews and other medical or radiological health product-specific activities and programs.
- The incumbent works in tandem with the Director to provide leadership and direction to the Division and its programs.
- Formulates, develops, and coordinates the administrative and regulatory activities related to medical or radiological health products, including administrative suspense and documentation management in accordance with applicable regulatory guidance.
- Represents the Office, Center Director and FDA (when necessary), and participates as the Office's scientific and regulatory authority, on all matters related to medical device regulatory issues in conferences, meetings and discussions with top level Agency and Departmental officials, regulated industry representatives, the medical scientific and academic Communities, national and international scientific and health related professional organizations, representatives from foreign governments, etc.
- Works with the Office Associate and Assistant Directors for Professional Development to provide or arrange for the needed development and training.

Professional Experience/Qualifications:

Candidates should have:

- Knowledge of organizational, operational, and programmatic concepts and practices applied by public, private, or nonprofit standard development and regulatory agencies and/or

organizations engaged in public health or other health-related areas of manufacturing standards development;
- Ability to clearly communicate complex technical ideas, regardless of the technical capacity of the audience;
- Strong inter-personal skills and ability to work as part of a team;
- Knowledge of the regulatory review process (pre- and/or postmarket);
- Knowledge and experience in regulatory science;
- Strong communication skills.

Desirable Qualifications/Experience:
- 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.

Basic Qualifications:
Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Physician, GP-0602: Must be a U.S. citizen with Doctor of Medicine (M.D.), Doctor of Osteopathic Medicine (D.O.) or equivalent from a school in the United States or Canada. The degree must have been approved by a recognized accrediting body at the time the degree was obtained.

A Doctor of Medicine or equivalent degree from a foreign medical school that provided education and medical knowledge substantially equivalent to accredited schools in the United States may be demonstrated by the Educational Commission for Foreign Medical Graduates, or a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country. Candidates for Civil Service or U.S. Commissioned Corps must possess a valid license to practice medicine in any state in the U.S. It is highly desired that the prospective candidate has eligible Board Certification.

Licensure: Applicant must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

How to Apply:
Prior to applying, please see the following instructions:
- Documents to submit: electronic resume or curriculum vitae, cover letter describing why you are uniquely qualified for this, and copy of transcripts
- Compile all applicant documents into **one combined document (i.e., Adobe PDF)**
- Include Job Reference code ***"DHT3 INFDT Assistant Director 2022"*** in the email subject line.

- Email comprehensive applicant package/document to CDRHRecruitment@fda.hhs.gov by **June 20, 2022**.

Conditions of Employment:

- One-year probationary period and 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.

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.

This is a confidential filing position, subject to FDA's prohibited financial interest regulation and may require the incumbent of this position to divest of certain financial interests. If selected, the employee must complete ethics requirements and file an annual financial disclosure report (OGE-450 form). For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at 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. 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.

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