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 IV (OHT4)
Division of Health Technology (DHT4A)

Position: Division Director (Supervisory Interdisciplinary Scientist)

Series: The position of Division Director (Supervisory Interdisciplinary Scientist) may be filled by candidates from the following occupational series: Biologist (0401), Microbiologist (0403), Physiologist (0413), Physician (0602), Nurse (0610), Consumer Safety Officer (0696), Veterinary Medical Scientist (0701), General Engineer (0801), Materials Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858) General Physical Scientist (1301), and Chemist (1320).

Location(s): Silver Spring, Maryland

Travel Requirements: This position requires occasional travel.

Application Period: November 24, 2020 through December 23, 2020

Salary: Salary is commensurate with education and experience.

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) 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 the industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Within CDRH, the Office of Product Evaluation and Quality (OPEQ) is responsible for setting strategy and overseeing all of the Offices of Health Technology 1-7. The of Office of Health Technology IV (OHT4) is responsible for the TPLC review of surgical and infection control medical devices, to include implementation of premarket review programs (e.g., 510(k), PMA, HDE, DeNovo, IDE, etc.), compliance and quality programs (e.g., Establishment Inspection Report, Regulatory Audit Reports, Recalls, Allegations of Regulatory Misconduct, Labeling, Enforcement Actions, etc.), and surveillance programs (e.g., Medical Device Reports, Post Market Surveillance Studies,

Safety Signals, etc.). OHT4 works closely with other offices on classification and reclassification activities, and the development of guidance documents.

Position Summary:
The Division Director, reporting directly to the OHT4 Office Director, partners in providing technical leadership and exercises scientific judgment in general surgery devices. Products areas include electrosurgical devices, minimally invasive surgery devices, light-based devices, robotically- assisted surgery devices, microwave, ultrasound, and cryosurgery devices, and point of care diagnostics, among others.

Supervisory Responsibilities:
Exercises significant responsibilities in dealing with officials of other units or organizations, or in advising management officials of higher rank.

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.

Coaches and mentors staff and helps sustain a strong and dynamic culture across teams within the Division, including organizational agility, staff empowerment and mobility, and collaboration.

Duties/Responsibilities:
The Division Director performs the following duties:

- Serves as a top scientific and technical expert and advisor and is recognized as a national authority and leader in the regulatory lifecycle of medical devices as they relate to the Center's premarket, compliance and quality programs, and post-market surveillance programs.
- Develops and coordinates a medical device program and implements the program to assure that the medical devices are safe and effective.
- Provides technical leadership and exercises exceptional scientific and engineering judgment in regulating various medical products.
- Provides technical consultation to the OHT4 Director, OPEQ Director, Center Director, and other high-level officials in the FDA, PHS, and HHS on program status, plans, trends and significant problems relative to the medical device area as called upon and when necessary.

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

- Directing, overseeing, and managing a multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with medical products (i.e. devices, biologicals, drugs, etc.);
- Interpreting and assessing scientific data and technical reports to determine the safety and effectiveness of medical products;
- Representing the organization on committees and at professional meetings, and conducting outreach to relevant stakeholder populations; and

- Leading strategic achievement of organizational goals, evaluating performance, and taking action to improve performance.

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

Desirable Qualifications/Experience:
Applicants with an advanced degree in science, engineering, or medical fields are highly desired.
- Experience with robotically-assisted surgical devices
- Prior scientific and medical expertise on medical devices and knowledge of medical device regulations.
- Excellent oral and written communication skills.
- Ability to work collaboratively with a diverse cadre of customers and healthcare stakeholders.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.

Additional Conditions of Employment:
- One-year 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.
- This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. 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. 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.

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 ***"2020-OHT4-DHT4A-043"*** in the email subject line.
- Email comprehensive applicant package/document to CDRHRecruitment@fda.hhs.gov by **Wednesday, December 23, 2020**.

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

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