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 Health Technology VI
Division of Joint Arthroplasty Devices

Position: Division Director, Joint Arthroplasty Devices

Series: This position may be filled by candidates from the following occupational series: Physician (602), Biologist (0401), Microbiologist (0403), General Health Scientist/Epidemiologist (0601), Nurse (610), Consumer Safety Officer (0696), Physical Scientist (1301), Physicist (1310), Chemist (1320), General Engineer (0801), Material Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858), Mathematical Statistician (1529), Statistician (1530)

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

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

Application Period: Thursday, June 24, 2021, through Friday, July 30, 2021

Salary: Salary starts at $163,962.00 and 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 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 the Center for Devices and Radiological Health (CDRH or Center) is to protect and promote the public health by performing essential public health tasks designed to ensure medical devices, diagnostic products, and radiological equipment, to include new and emerging technologies, are safe, reliable, and effective for the American people.

Within CDRH, the Office of Product Evaluation and Quality (OPEQ) is responsible for setting strategy and overseeing the Offices of Health Technology I - VII, Office of Clinical Evidence & Analysis (OCEA), Office of Regulatory Programs (ORP), Quality & Analytics Staff, Clinical & Scientific Policy Staff, Strategic Initiatives Staff, Regulation Policy & Guidance Staff, and

Operations Staff**.** This position resides within the Office of Health Technology VI (OHT VI or Office), in the Division of Joint Arthroplasty Devices (DJAD or Division). Using a focused Total Product Lifecycle (TPLC) approach, OHT VI ensures quality end-to-end device evaluation of orthopedic devices, and the consistent interpretation and application of regulatory policy and guidance

Position Summary:
CDRH is seeking a strategic, innovative, and team-oriented Division Director who is dedicated to improving health outcomes and the quality of life of patients through the advancement of assistive, implantable, and therapeutic orthopedic medical devices. In this critical supervisory position, you will report directly to OHT VI Office Director and will be responsible for providing expert scientific and technical leadership, exceptional administrative management, and exercising sound scientific, clinical, and evidenced-based technical judgement in the review of prosthetic orthopedic devices and associated arthroplasty surgical instrumentation and systems.

Supervisory Responsibilities:
As a creative and collaborative leader, you will manage and grow high-performing, multidisciplinary scientific, technical, and professional teams in support of advancing the strategic vision of the Office. As such, you will monitor and evaluate the technical performance of Division staff who serve as experts in their respective fields. You will also devote at least 25 percent of your time towards coaching, mentoring, and supervising your employees.

Duties/Responsibilities:
As the Division Director you will perform the following:

- Serve as a recognized national expert and authority in the regulation of arthroplasty medical devices encompassing the entire product lifecycle.
- Provide expert consultation to Office, Super Office, and Center leadership on programmatic plans, trends noted in the clinical, patient, and scientific communities, as well as industry, significant concerns and adverse event reported data regarding orthopedic arthroplasty medical devices and related products regulated by the Center.
- Collaborate in the development, coordination, and implementation of policies and programmatic norms rooted in science to assure medical products, especially those novel in nature, with emerging technologies, are safe, effective, reliable, and available for patients and providers.
- Collaborates with the OHT VI Office Director to ensure uniform adoption, implementation, and consistent application of OPEQ and Center-wide guidance, initiatives, and policies regarding regulatory oversight of medical devices within the scope of DJAD.
- Draft decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, manufacturing, and reliability concerns.
- As a recognized expert, collaborate with colleagues across the Office, Center, and Agency to develop guidance documents, policies, and standards regarding the use of clinical outcome assessments in the evaluation of orthopedic joint arthroplasty medical devices.

- Represent the Office and Center at scientific, international standard organization, and other professional meetings, conferences, stakeholder meetings, working groups, and FDA advisory panels.
- Ensure the uniformed high quality and consistency of clinical, scientific, and technical reviews across the total product life cycle for orthopedic arthroplasty medical devices assigned to the Office.
- Partner with OPEQ's senior leadership team, as appropriate, to leverage the necessary expertise on pre-market, compliance, and surveillance, as well as clinical, scientific, and regulatory policy expertise for reviews.
- Collaborate with the OHT VI Office Director to plan, organize, and establish or realign assignments, priorities, and work projects to advance new initiatives and/or programmatic and regulatory objectives for the Division and Office.
- Engage and collaborate with patient advocacy groups, industry, healthcare, and scientific communities to address all adverse event data and medical concerns associated with orthopedic arthroplasty medical devices.

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

- Managing and leading diverse multidisciplinary staff in a large and complex organization responsible for the scientific, technical, public health, and regulatory activities associated with FDA regulated products
- Evidence of leading strategic achievement of organizational goals, evaluating workforce performance, and deploying effective interventions to improve organizational outcomes
- Analyzing and interpreting regulatory policy and guidance to share expertise and advise leadership on highly complex and precedent setting public health matters.
- Developing policies, protocols, guidance documents, and/or recommendations which speak to the safety, efficacy, and reliability of medical products.
- Demonstrated proficiency in written and verbal communication skills, as well as teamwork
- Representing your Division, Office, and Center on Agency working groups, at professional associations, industry and stakeholder meetings, and serve on FDA advisory committees

Desirable Qualifications/Experience:

- Advanced degrees in applied, life, and/or physical sciences, such as Biology, Chemistry, Engineering, Physics, or medical fields are highly desired
- Scientific and/or clinical expertise in the utilization of orthopedic arthroplasty medical devices
- Professional knowledge and understanding of current FDA regulations, policies, and procedures pertaining to safe, reliable, and effective medical devices
- Ability to construct and work effectively within a multidisciplinary team environment

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

Conditions of Employment:

- A 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.

How to Apply:

Submit an electronic resume or curriculum vitae, cover letter containing a brief summary of scientific accomplishments, SF-50 (if applicable), and a copy of unofficial transcripts all in one document (**Adobe PDF**) to CDRHRecruitment@fda.hhs.gov, with Job Reference code ***"2020-OHT-6-DHT6A-M4-P-164"*** in the subject line. Applications will be accepted through **July 30, 2021.**

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.

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