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 VI (OHT VI)
Division of Joint Arthroplasty Devices (DJAD)

Position: Assistant Director - **Hip Arthroplasty Devices Team**

Series: This position may be filled by candidates from the following occupational series: Physician (0602), Biologist (0401), Microbiologist (0403), General Health Scientist/Epidemiologist (0601), Nurse (0610), 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: Monday, November 29, 2021, through Monday, January 10, 2022

Salary: Salary starts at $122,530.00 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 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.

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 Assistant Director 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, public health-focused, and team-oriented Assistant Director who is dedicated to improving health outcomes and the quality of life of patients through the advancement of arthroplasty medical devices and systems. In this critical supervisory position, you will report directly to the DJAD Director and will be responsible for providing expert scientific and technical leadership, exceptional administrative management, and exercising sound evidenced-based judgment and decision-making in the review of hip arthroplasty surgical instrumentation and systems.

Supervisory Responsibilities:
As a collaborative leader, you will manage and grow a high-performing, multidisciplinary scientific, technical, and professional team in support of advancing the strategic vision and regulatory mission of the Division and Office. As such, you will monitor and evaluate the technical performance of your Team 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 Assistant Director you will perform the following:

- Utilize expert scientific and technical knowledge and vast regulatory expertise to serve as an authoritative advisor for the DJAD Director, OHT VI Director, and OPEQ on hip arthroplasty instrumentation and systems, both novel and existing, encompassing the entire product lifecycle.
- Provide expert consultation to Division and Office leadership on programmatic plans, health care community, scientific, and industry-related trends, significant concerns, and adverse event reported data regarding hip arthroplasty medical devices regulated by the Division.
- Collaborate with team members, colleagues, and Division leadership to ensure the uniformed adoption, implementation, and consistent application of OPEQ and Division-wide guidance, initiatives, and policies regarding regulatory oversight of hip arthroplasty instrumentation, devices, and systems.
- Ensures the uniformed high quality and consistency of scientific and regulatory reviews across the total product lifecycle of hip arthroplasty medical devices assigned to the Division.
- Provide comprehensive support to product advisory panels, industry, and consultants and coordinate activities regarding classification actions, petitions, premarket notifications (510(k)s), premarket approval applications (PMAs), Product Development Protocols, De Novos, 513(g)s, Investigational Device Exemptions (IDEs), Humanitarian Device

Exemptions (HDEs) and Pre-submissions (Q-subs) with Center and Agency components or other organizations, when appropriate.
- Coordinate and partner with colleagues and leadership across the Division and Office, as appropriate, to leverage the necessary expertise for pre-market, compliance, and surveillance, as well as clinical, scientific, and regulatory policy expertise for reviews.
- Draft decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, performance, and reliability concerns.
- Collaborate with Division leadership 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 hip arthroplasty instrumentation, devices, and systems.

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
- Enforcing policies, protocols, guidance documents, and/or recommendations that speak to the safety, efficacy, and reliability of medical products.
- Analyzing, interpreting, and sharing regulatory policy expertise with review teams and advising Division and Office leadership on scientific matters that may be highly complex, precedent-setting, or controversial in nature.

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 hip arthroplasty instrumentation, medical devices, and systems
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders
- Artful in effectively interpreting and presenting complex information and concepts, in both written and oral formats

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, a 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-008**"* in the subject line. Applications will be accepted through **January 10, 2022.**

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 factors.
- 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.