Introduction: The Center for Devices and Radiological Health (CDRH or Center), the medical devices scientific and regulatory arm of the U.S. Food and Drug Administration (FDA), now welcomes applications from Orthopedic Surgeons to join our medical device review teams in the Office of Product Evaluation and Quality’s (OPEQ) Office of Health Technology 6 (OHT6). We are seeking Orthopedic Surgeons who specialize in the diagnosis, treatment, and correction of upper extremity disorders, particularly those involving the shoulder and elbow. These positions reside in the Division of Health Technology 6A (DHT6A or Division), which is responsible for the Total Product Life Cycle (TPLC) review of joint arthroplasty devices (instrumentation and systems), both novel and existing.

Position Summary: DHT6A is recruiting Orthopedic Surgeons, who are dedicated to improving the health outcomes and quality of life patients through the advancement of elbow and shoulder arthroplasty medical devices and systems. Specifically, we are seeking experienced Orthopedic Surgeons to serve as clinical experts on our medical device review teams. You will have the opportunity to apply your vast diagnostic and surgical expertise to conduct comprehensive evaluations of clinical studies, technical data, and post-market surveillance reports of orthopedic medical devices and equipment used to diagnose, treat, manage, and correct disorders of the elbow and shoulder. You will collect and synthesize data from multiple sources to offer expert recommendations and guidance to improve the safety, quality, reliability, and performance of orthopedic medical devices and instrumentation within the Division’s portfolio. Additionally, you will exercise sound evidenced-based judgement and decision-making in the review of elbow and shoulder arthroplasty surgical instrumentation and systems and when responding to inquiries from the Agency, Department, industry, patient advocacy and healthcare professional organizations, other government entities, as well as stakeholders, both internal and external.

Duties/Responsibilities: As a Physician (Orthopedic Surgeon), you will perform the following duties:

- Assess the safety, performance, effectiveness, and reliability of elbow and shoulder arthroplasty devices encompassing the total product life cycle.
- Provide expert clinical consultation to Division and Office leadership pertaining to industry related trends, significant concerns, and adverse event reported data, as well as patient and provider reported outcomes, regarding elbow and shoulder arthroplasty medical devices regulated by the Office.
- Evaluate manufacturers’ methodology, study designs, as well as clinical, scientific, and technical data to determine the validity and completeness of safety, effectiveness, performance, and reliability claims.
- Provide clinical, scientific, technical, and regulatory guidance and consultation to industry, academia, and health care professionals on the safety, effectiveness, performance, and reliability of elbow and shoulder arthroplasty instrumentation and systems.
- Keep abreast of current events, findings, and updates in medical device law and regulations through the review of scientific and legislative literature, attending professional, scientific, and standards meetings, and by collaborating with regulatory policy experts.
- Engage and collaborate with patient advocacy groups, as well as industry, healthcare, and scientific communities to address all adverse event data and medical concerns associated with elbow and shoulder arthroplasty instrumentation, devices, and systems.
- 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.
- Provide comprehensive support to product advisory panels, industry, and consultants and assist in coordinating 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.
Professional Experience/Key Requirements: To qualify for this position, you must demonstrate in your resume the necessary experience for this position, which is equivalent to the following:

- Expertise in the general aspects of orthopedics, sports medicine, trauma, and/or joint replacement.
- Ability to collaborate with a multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with orthopedic medical devices and products.
- Ability to interpret and assess scientific data and technical reports to determine the safety, effectiveness, and reliability of orthopedic medical devices and products.
- Ability to represent the organization on committees and at professional meetings, conducting outreach to relevant stakeholder populations, and leading strategic achievement of organizational goals.

Salary: Salary is equivalent to GP-0602-14, plus physician market pay (Title 38), and is commensurate with education/experience. U.S. Public Health Service Commissioned Corps Officers may also apply.

Basic Qualifications: Physician, (GP-0602): A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates, a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

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. It is highly desired that the prospective candidate has eligible Board Certification.

Additional Conditions of Employment

- United States Citizenship is required.
- This position requires occasional travel.
- 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.
- To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

Application Period: Wednesday, September 7, 2022, through Friday, October 7, 2022

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

How to Apply: We invite you to apply today by completing the following steps:
1. Submit your electronic resume or curriculum vitae to CDRH Recruitment at CDRHRecruitment@fda.hhs.gov, Job Reference Code: 2020-OHT6-DHT6A3-001

2. Create/Log-in to your USAJOBS account and review the official job opportunity announcement located on USAJobs.gov at https://go.usa.gov/xtsuQ. Applications **MUST** be received by applying to the official job opportunity announcement located in the link above.

3. Required documentation should include: a copy of your current, active, unrestricted medical license and a copy of your Doctor of Medicine transcripts (official/unofficial) or ECFMG. Your transcripts must show completion/conferred date. Additional supporting documentation may include a bibliography, summary of research accomplishments, and names/contact information of three references.

   **Visit CDRH Jobs to see additional opportunities.**

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