Job Title: Physician (Orthopedic Surgeon)
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)
Office of Health Technology VI (OHT6)/ Office of Orthopedic Devices

Summary:
The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) and being filled under FDA's Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA's ability to recruit and retain scientific, technical, and professional experts in certain occupational series that "support the development, review, and regulation of medical products." The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

Become a part of the Department that touches the lives of every American.
At the Department of Health and Human Services (HHS) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Devices and Radiological Health 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. The Office of Product Evaluation and Quality 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. The Office of Health

Technology VI (OHT6) is responsible for the total product lifecycle (TPLC) review of orthopedic medical devices.

Overview: **This is a full-time position**

Open & Closing Date: November 18, 2024 – December 18, 2024
Salary Range: $165,000.00 - $262,150.00
Band: AD-C
Occupational Series: Physician (0602)
Duty Location: Various duty station(s)
Remote Job: Yes
Travel Required: Yes, may require travel up to 25%
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: **Full-Time**
Competitive Service: Competitive
Promotion Potential: AD-C
Supervisory Status: No
Security Clearance: Security Clearance
Drug Test: No
Licensing Required: No
Bargaining Status: 3591
Position Designation: Public Trust
Trust Determination Process: Moderate Risk

This job is open to: **Open to the Public**

Note: Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Duties

****This is a full-time position****

Reporting directly to the Assistant Director, the Physician (Orthopedic Surgeon) will serve as a clinical authority and technical expert for the review of cutting-edge orthopedic medical devices, implants, techniques, instrumentation, and surgical systems and will play a pivotal role in advancing the mission of the Center's Total Product Lifecycle Advisory Program (TAP). TAP is designed to spur rapid development and wide-spread use of "breakthrough" lifesaving and health improving medical devices and products, support patient access and ensures the safety, effectiveness, and reliability of these products throughout the total product lifecycle. The Physician will lead solution-focused engagement activities with medical device developers, members of the healthcare and standards communities, patients, and patient advocacy organizations, and other non-FDA stakeholders to ensure timely and sustainable patient access to these critical devices. Additionally, the incumbent will serve as an advisor to the Office Director, Super Office Director, and other OPEQ Offices, as well as CDRH leadership. Further, the incumbent will provide advice and leadership to scientific, clinical, professional, and

technical staff throughout OHT 6, regarding orthopedic medical devices and systems. The Physician will also perform the following duties:

- Serve as an authority on the latest developments in health care policy and the orthopedic medical device industry. As such, conducts regulatory policy reviews related to the development aspects of orthopedic medical devices, diagnostic equipment, surgical instrumentation, and systems used in this medical device space.
- Provide oral and written consultations for various types of regulatory submissions across a wide range of orthopedic medical device types related to fracture fixation, joint replacement, reconstruction, trauma, sports medicine, limb lengthening, and disorders of the spinal, hand, and upper and lower extremities.
- Foster patient partnerships with capabilities to collaborate with MedTech industry sponsors, innovators, and FDA to provide insights on unmet needs, disease burden, real world experiences and preferences within the target patient population.
- Utilize clinical expertise and technical knowledge to serve as an authoritative voice and principal advisor to OHT 6 Assistant Directors and the OHT6 Office Director on matters regarding orthopedic medical devices, diagnostic equipment, instrumentation, surgical systems, and products, encompassing the entire product lifecycle.
- Provide authoritative analysis of the scientific data submitted in orthopedic medical device regulatory submissions and assists in the interpretation of post-market adverse event data.
- Offers evidence-based recommendations regarding classification and petitions for the reclassification of new orthopedic medical devices, instrumentation, and systems, as well as identifies areas where standards need to be developed and/or revised.

Requirements

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959, must be registered with the Selective Service. Please go to http://www.sss.gov for more information.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.

- Background Investigation Requirement: All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.

Qualifications

In order to qualify for this Physician (Orthopedic Surgeon), AD-0602, opportunity, you must meet the following requirements by 11:59pm EST on **Wednesday, December 18, 2024.**

Basic Qualification Requirements:

- One (1) year of supervised experience providing direct service in a clinical setting specialized in general orthopedics, sports medicine, osteoporosis, trauma, arthritis, disorders of the spine, hand, and upper and lower extremities. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

Education:

- A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent;
- Degree from Foreign Medical School: 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.

How to Apply:

****This is a full-time position****

Submit an electronic resume or CV, cover letter containing a brief summary of scientific accomplishments, SF-50 (if applicable), and a copy of unofficial transcripts in one document (**Adobe PDF**) to CDRHRecruitment@fda.hhs.gov, with Job Reference code ***"2024-OHT6-Physician"*** in the subject line. Applications will be accepted through **Wednesday, December 18, 2024.**

Please follow all instructions carefully. Errors or omissions may affect your eligibility.