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 6 (OHT6)

Position: Physician (OHT6)

Application Period: 7/18/23 – 10/30/23

Location(s): Silver Spring, MD

Salary: Starts at $165,000 and is commensurate with qualifications and experience.

CURES Band(s): Bands C

Area of Consideration: U.S. Citizens

Travel Requirements: Up to 25%

Work Schedule: Full Time

Bargaining Unit: 3591

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), a major regulatory component of the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS), is inviting applications for ***Physician (OHT6)*** in the Office of Product Evaluation and Quality (OPEQ), Office of Health Technology 6 (OHT6) is responsible for the total product lifecycle (TPLC) review of orthopedic devices.

As a Physician reporting directly to the Assistant Director, you will serve as a clinical authority and technical expert for the review of cutting-edge orthopedic devices. You will also serve as a Physician advisor to the Office Director, Super Office Director, and other OPEQ and CDRH leadership. Also, the incumbent provides advice and leadership to a scientific, clinical, professional, and technical staff throughout the Office.

Duties/Responsibilities

The ***Physician (OHT6)*** duties include, but are not limited to the following:

- Serve as an OHT6 focal point and primary contact for medical device clinical issues.
- Provide oral and written consultations for various types of regulatory submissions across a wide range of orthopedic devices related to diverse clinical areas including but not limited to fracture fixation, joint arthroplasty, extremity reconstruction, cartilage repair, spinal disorders, and stereotaxic devices.
- Play a significant role in clinical study design, Serve as the clinical authority in providing support to device specific offices in reviewing and evaluating clinical and research

findings, real-world clinical evidence, analyses, laboratory and clinical behavior, and the impact of these factors and properties on the new safety and effectiveness of medical devices and provides clinical and senior leadership and guidance in review policy procedures, with particular emphasis on clinical testing and evaluation.

- Provide authoritative analysis of the scientific data submitted in orthopedic device regulatory submissions and assist in the interpretation of post-market adverse event data.
- Provide expert and authoritative advice, guidance, assistance, interpretations, consultations and recommendations to senior Agency and Departmental officials, program directors, scientific and professional personnel, industry, representatives, and intra/inter-governmental counterparts.
- Lead in the planning and development of clinical policy initiatives and make recommendations that have major impacts to the Agency's broad mission of protecting and promoting the Nation's public health.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
   a. **Qualified** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
   b. **Outstanding** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

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

- Clinical experience related to the practice of orthopedic surgery and current knowledge related to the basic science behind clinical decisions related to orthopedic surgical procedures.
- Experience in advising, training, and guiding multi-disciplinary staff in a clinical, public health or regulatory environment.
- Expertise in interpreting and presenting complex scientific, medical, clinical, and/or regulatory information and concepts, in both written and oral formats for a variety of audiences.
- Ability to build collaborative and mutually beneficial working relationships with a wide range of customers and stakeholders.
- Possession of a Doctor of Medicine or Doctor of Osteopathy from a school in the United States or Canada approved by a recognized accrediting body in the year of the applicant's graduation.

Desirable Qualifications/Experience:

- Excellent leadership and communication skills.
- Ability to work collaboratively with a diverse cadre of customers and stakeholders.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.
- Experience using Microsoft Office and basic computer skills
- Diplomates of the American Board of Orthopaedic Surgery is a plus
- Expertise related to upper extremity musculokeletal conditions with a particular interest in shoulder joint disorders and devices are encouraged to 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.

How to Apply

Prior to applying, please see the following instructions:

- Submit an electronic resume or curriculum vitae, a cover letter containing a brief summary of accomplishments and why you're interested in this position.
- Include Job Reference code ***"Physician (OHT6)"*** in the email subject line.
- Email applicant package to CDRHRecruitment@fda.hhs.gov.
- **Visit CDRH Jobs to see additional opportunities.**

Conditions of Employment

- United States Citizenship is required.
- One-year supervisory 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.

Public Health Services Commissioned Corps Officers

PHS Commissioned Corps Officers interested in performing the duties of this position within the Commissioned Corps may apply to this announcement. Officers must follow the instructions for how to apply and include their most recent orders in addition to the required documents. If selected, candidates will be referred to (CC) personnel and not as candidates for a Cures appointment.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information, please visit the FDA Ethics web page: 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.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.