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 3 (OHT3)
Division of Reproductive, Gynecology, and Urology Devices (DHT3B)

Position: Physician - Urologist (OHT3)

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

Area of Consideration: U.S. Citizens

Travel Requirements: This position requires up to 25% or less.

Application Period: February 1, 2023 through March 3, 2023

Salary: Salary is commensurate with education and experience and starts at $165,000.

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 a Physician-Urologist in the Office of Health Technology 3 (OHT3). OHT3 is responsible for the total lifecycle (TPLC) review of reproductive, gastro-renal, urological and general hospital devices and the CDRH Human Factors program. DHT3B is specifically responsible for the TPLC review of reproductive, gynecologic, and urologic devices.

Position Summary:
As a Physician (Urologist) in OHT3/DHT3B, you will be working on projects involving the full range of medical devices and their accessories used in urological procedures (e.g., peripheral and sacral neurostimulators, surgical mesh for stress urinary incontinence, devices for treatment of voiding dysfunction, prostate cancer treatment devices, etc.). You will review proposed clinical trial protocols to ensure that trials are capable of collecting valid scientific evidence while sufficiently protecting patient safety, analyze the results of clinical trials to determine whether they support the safety and effectiveness of a given product, aid in development of scientifically sound clinical review policy for urological devices, evaluate post market device safety issues/recalls and participate in outreach to device manufacturers and physician groups on clinical topics.

Duties/Responsibilities:
The Physician-Urologist also performs the following duties:

- Review total product life-cycle actions (premarket, compliance, and post-market

surveillance) related to urological devices. Actions may include 510(k), PMA, De Novo, IDE, pre-submission, submission issue request, 513(g), MDRs, recall and complaint submissions.

- Develop, modify, and evaluate guidelines concerning clinical data required in urology medical device actions to be submitted to the Agency. In this capacity, the incumbent participates as a member of a team of experts to develop agency- or center-wide guidelines applicable to the regulation of relevant urological medical devices.
- Present reviews, conclusions, opinions, and recommendations to outside stakeholders on submissions and review issues. These discussions will include key issues pertaining to the safety and effectiveness of the urological medical device(s), outlines of deficiencies, and recommendations for approval or non-approval of the device or the submission.
- Enhance professional career development by collaborating with engineers, clinicians, and scientists to better understand medical device problems. Keep abreast of current events and findings and changes in medical device law and regulations through review of scientific and legislative literature, personal contact with relevant authorities, and by attending scientific meetings.

Professional Experience/Key Requirements:

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

- Expertise in urology, urinary incontinence (e.g., surgical mesh, neurostimulators) and/or female pelvic medicine and reconstructive surgery is highly desired.
- Ability to collaborate with a multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with medical products (i.e., devices, biologicals, drugs, etc.).
- Ability to interpret and assess scientific data and technical reports to determine the safety and effectiveness of medical 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.

Desirable Qualifications/Experience:

- Extensive experience in and knowledge and management of clinical research, including associated regulations governing clinical research/trials.
- Prior scientific and medical expertise on medical devices; professional knowledge and understanding of current FDA regulations, policies, and procedures pertaining to safe and effective medical devices.
- Expert skill in written and verbal communications to prepare written documents and findings and to present findings and conduct briefings.
- Knowledge of the regulatory total product lifecycle (TPLC) review process of urology devices including: implementation of premarket review programs (e.g., 510(k), PMA, HDE, De Novo, IDE, etc.), compliance and quality programs (e.g., Establishment Inspection Report, Regulatory Audit Reports, Recalls, Allegations of Regulatory Misconduct, Labeling, Enforcement Actions, etc.), and surveillance programs (e.g., Medical Device Reports, Post Market Surveillance Studies, Safety Signals, etc.).

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, copy of your active medical license, copy of your transcripts (unofficial).
- Include Job Reference code ***"Physician-Urologist (OHT3)"*** 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 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.
- 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.

This is a bargaining unit position.

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.

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.

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