

Staff Fellow - Interdisciplinary Engineer (OHT3)

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, is inviting applications for a **Staff Fellow (Interdisciplinary Engineer)** to serve in the Incontinence and Female Urological Devices Team of the Division of Health Technology 3B ([DHT3B](#)), Office of Health Technology III ([OHT3](#)). The division is responsible for the total lifecycle (TPLC) review of reproductive, gynecology and urology devices.

POSITION SUMMARY: DHT3B is recruiting a Staff Fellow to serve in the multidisciplinary (e.g., clinical, engineering, statistical, microbiological, and toxicological) Incontinence and Female Urological Devices Team, which is responsible for premarket and postmarket review of a variety of urological devices including neurostimulators, surgical mesh, urethral bulking agents, urinary catheters, urethral and ureteral stents, and vascular embolic agents and ablative therapies used in the treatment of prostate disease. These devices are often novel and represent state-of-the-art technologies and therapies.

DUTIES / RESPONSIBILITIES: As a Staff Fellow, you will perform the following duties:

- Evaluate the safety and effectiveness of a variety of urological medical devices through total product lifecycle review of bench, animal, and clinical protocols and data, concluding with written analyses and recommendations.
- Provide guidance to industry and investigators on regulatory processes and expectations regarding bench testing and study design through meetings, conference presentations, etc.
- Engage with FDA stakeholders, including patients, providers, and industry, to support advancement of urological medical devices.

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:

- Electrical engineering experience in medical devices throughout the total product lifecycle is highly desired.
- Experience managing scientific projects and supporting diverse stakeholders in order to reach project milestones.
- Familiarity with software development/verification and validation, technical software development concepts, cybersecurity risk management, and/or understanding of security architecture is highly desired.
- Exceptional analytical skills (qualitative and quantitative).
- Ability to effectively interpret, assess and present complex scientific and technical 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 diverse cadre of customers and stakeholders.

BASIC QUALIFICATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: [General Engineer \(0801\)](#); [Material Engineer \(0806\)](#); [Electrical Engineer \(0850\)](#); [Bioengineering and Biomedical Engineering \(0858\)](#).

ADDITIONAL QUALIFICATIONS: To qualify as a Staff Fellow, you must: be a US Citizen, Permanent Resident, or Non-Citizen with residency status in the U.S., three (3) out of the last five (5) years; possess a doctoral-level degree from an accredited institution of higher learning, including: Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or other research doctoral-degree widely recognized in U.S. academe as equivalent to a Ph.D.. (*In limited instances non-doctoral candidates, and/or candidates with less experience may be acceptable*).

FOREIGN EDUCATION: Candidates who have completed part or all of their education outside the United States must, in order to meet qualification requirements, have their foreign education evaluated by an accredited organization to ensure the foreign education is comparable to education received in the United States. It is the responsibility of the candidate or employee to provide written proof of his/her foreign education accreditation prior to appointment or placement in a different occupational series from which placed. *For further information, visit the [U.S. Department of Education - Foreign Education Evaluation](#).*

CONDITIONS OF EMPLOYMENT

- One-year probationary period may be required.
- This position is for a **two-year** appointment and will be filled through [FDA's Staff Fellowship Program](#)
- Background and/or Security investigation required.
- Applicants who are U.S. Citizens and born male, on (or after) 12/31/1959, must be registered with the [Selective Service System](#) OR have an approved exemption.
- 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 additional information, please visit the [FDA Ethics and Integrity Office](#).
- 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.

LOCATIONS: [FDA's White Oak Campus](#) in Silver Spring, Maryland

SALARY / BENEFITS: Salary is commensurate with education and experience. A comprehensive benefits package is offered to most Federal employees. For additional benefit information click [here](#).

HOW TO APPLY: Prior to applying, please see the following instructions:

- Submit an electronic resume or curriculum vitae and a cover letter describing why you are uniquely qualified for this job.
- Include Job Reference code **"2020-OHT3-DHT3B-011"** in the email subject line.
- Email applicant package to CDRHRecruitment@fda.hhs.gov.
- Applications and all supporting documentation will be accepted through **September 3, 2022**.
- Visit [CDRH Jobs](#) to see additional opportunities.

The United States Government [equal opportunity employer](#) and does not discriminate 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.