U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Staff Fellow (Research Engineers)

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), welcomes applications from Engineers of all specializations, for our Staff Fellow (Interdisciplinary Research Engineer) positions in the Office of Science and Engineering Laboratories (OSEL). These positions are located in the Division of Biomedical Physics (DBP or Division). This Division helps drive the FDA mission by performing best in the world regulatory science on the biophysical interactions between medical devices and the human body.

POSITION SUMMARIES: DBP is recruiting Staff Fellows (Interdisciplinary Research Engineers) from all engineering specializations to serve as integral members of its research team dedicated to advancing and leading regulatory science initiatives and projects to accelerate patient access to safe, effective, and innovative medical devices. Specifically, these Staff Fellows will conduct research and experiments to build test methods and understand the safety and performance of interoperable systems of medical devices. This will involve configuring simulation environments for integrated medical device systems and developing and assessing computational and hardware-in-the-loop test methods for the evaluation of applications (e.g., multiparameter patient monitoring alarm algorithms, physiologic closed-loop controllers) running in integrated clinical environments. These positions will have the potential for significant interaction with VA Ventures, the Veterans Health Administration's (VHA) medical device innovation center.

DUTIES/RESPONSIBILITIES: As Staff Fellows (Interdisciplinary Research Engineers), you will perform the following duties:

- Serve as a technical authority in the scientific and technical analysis of medical device safety, effectiveness, performance, security, and reliability.
- Provide an authoritative analysis of scientific and technical data submitted to the Agency for review.
- Develop new and innovative approaches to scientific testing required for medical device reviews by FDA.
- Generate written technical and scientific documents for peer-reviewed publications and consulting support activities.
- Utilize expert scientific and technical knowledge to serve as an advisor and consultant on regulations and policies involving complex and high priority matters affecting the regulation of new medical devices with emerging technologies.
- Draft and present reviews, conclusions, opinions, and recommendations to OSEL, CDRH, FDA, industry, advisory panels, consultants, and other stakeholders focused on public health, in both oral and written formats.

PROFESSIONAL EXPERIENCE/KEY REQUIREMENTS: To qualify for these Staff Fellow positions, at minimum, you must demonstrate the following in your resume:

- Experience in reviewing, analyzing, and using scientific data and/or other information to advance and convey understanding of medical devices.
- Ability to develop project plans and manage timely execution of project deliverables and timelines.
- Ability to participate in and contribute collaboratively within multi-disciplinary teams and working groups to address and resolve difficult or controversial research and regulatory challenges.
- Excellent oral and written communication skills demonstrated through the development and delivery of presentations and written materials.

DESIRED EXPERIENCE/QUALIFICATIONS: Please document your background and specialized experience in your resume:

- Experience designing and conducting hardware-in-the-loop (real-time) testing of medical devices and health technology systems, including physiologic closed-loop controllers and/or interoperable patient monitoring algorithms
- Experience designing and/or using non-clinical testing tools (e.g., physiologic signal simulators, computational models) for medical equipment
- Experience programming and connecting medical devices and other electronic data systems
- Experience applying signal processing and machine learning to physiologic signals (e.g., electrocardiogram, photoplethysmography) and/or other types of time-series medical data
- Knowledge of medical instrumentation data interfaces and data taxonomy
- Knowledge of cardiorespiratory physiology.

BASIC QUALIFICATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: Biomedical Engineering (0858), Computer Engineering (0854), Computer Science (1550), Electrical Engineering (0850), Electronics Engineering (0855), Mechanical Engineering (0830)

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 **three-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.
- All candidates must meet applicable security requirements which include a background check and a minimum of three (3) out of the past five (5) years' residency status in the US. If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security reinvestigation or supplemental investigation may be required at a later time. Applicants are also advised that all information concerning qualifications is subject to investigation. False representation may be grounds for non-consideration, non-selection, or appropriate disciplinary action.

FDA U.S. FOOD & DRUG ADMINISTRATION
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- 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: Seattle, Washington

SALARY: Salary is commensurate with education and experience.

BENEFITS: 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 ***"2023-OSEL-DBP-054"*** in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications and all supporting documentation will be accepted through **July 31, 2023.**
- Visit CDRH Jobs to see additional opportunities.
- Contact Denise Townsend for questions: Denise.Townsend@fda.hhs.gov

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.