

Staff Fellow (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 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 associated with interoperable patient monitoring and physiologic closed-loop control medical device systems and wireless communications in medical device applications. More detailed summaries of each position are below:

Interoperable Patient Monitoring Systems Research Engineer (M5-051): DBP is seeking engineers with the requisite research experience to develop and assess new evaluation methodologies for interoperable medical device and health technology data systems for applications such as multiparameter patient monitoring alarm algorithms or physiologic closed-loop control.

Wireless Communications Research Engineer (M5-052): DBP is seeking engineers with the requisite research and practical application experience to construct, implement, model, simulate, and test wireless technology applications associated with health care technologies.

DUTIES/RESPONSIBILITIES: As Staff Fellow, 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.

To qualify for each position, in the identified research area, please see the specific professional experiences and key requirements:

DESIRED EXPERIENCE/QUALIFICATIONS: Please document your background and specialized experience for our **Interoperable Patient Monitoring Systems Research Engineer (M5-051)** in your resume:

- Experience with design of electronic systems for acquiring and processing medical data and/or real-time testing of medical device and health technology systems.
- Experience in developing and conducting non-clinical methods (e.g., physiologic signal simulators, computational modeling) for testing patient monitoring and/or other medical device system.
- Knowledge of medical instrumentation data interfaces and data taxonomy.
- Knowledge of and experience with signal processing and machine learning applied to physiologic signals (e.g., electrocardiogram, photoplethysmography) and/or other types of time-series medical data.

DESIRED EXPERIENCE/QUALIFICATIONS: Please document your background and specialized experience for our **Wireless Communications Research Engineer (M5-052)** in your resume:

- Experience in developing, implementing, modeling, simulating, and/or testing wireless technology in healthcare applications or other relevant scenarios (e.g., industrial automation, manufacturing, connected vehicles).
- Experience with cellular communication systems (e.g., LTE, 5G), their components in the radio access and core networks, and associated enabling technologies (e.g., MIMO, Network Slicing), as well as having a working knowledge of local area wireless communication technologies (e.g., Wi-Fi, Bluetooth, RFID).
- Experience with data collection and analysis software tools related to wireless communication technology (e.g., Wireshark, MATLAB, Python, LabVIEW).

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.
- 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: Silver Spring, Maryland

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, with your position of interest, describing why you are uniquely qualified for this job.
- Include the Job Reference code in the email subject line:
 - **DBP Staff Fellow - Interoperable Patient Monitoring Systems Research Engineer (M5-051)**
 - **DBP Staff Fellow - Wireless Communications Research Engineer (M5-052)**
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications and all supporting documentation will be accepted through **September 30, 2022**.
- 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.