

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Science and Engineering Laboratories (OSEL)

Position Title: Electrical/Biomedical/Mechanical Engineer (Staff Fellow)

Location: Silver Spring, Maryland

Application Period: September 24, 2021 through October 24, 2021

Salary Range: \$87,198 - \$134,798 (commensurate with education and experience)

Position Information: Full-Time – appointment term of 3 years, with possibility of being extended.

Who may be considered: US Citizens; Permanent Residents; and Non-Citizens

Introduction: The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective. The mission of CDRH is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States. OSEL is dedicated to promoting innovation for the development of new lifesaving medical devices. OSEL is composed of scientists and engineers who have a broad diversity of expertise from microbiology to artificial intelligence and machine learning. The Division of Biomedical Physics (DBP) within CDRH's OSEL, 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 Summary: The DBP has multiple openings for staff scientists/engineers in the Human-Device Interaction and Patient Monitoring and Control Programs. Candidates should have a strong background in one of the following areas:

- wearable sensors applied to capturing and monitoring human movement and physiologic data with experience in one or more of the following:
 - o biomechanics of human movement;
 - o 3D motion capture acquisition and analysis;
 - o artificial intelligence and machine learning applied to human movement and physiologic time-series data;
 - o development of computational tools for analysis of movement and physiologic data;
 - o statistical signal processing of human movement and physiologic signals.
- Signal processing and machine learning algorithms for processing physiologic signals (e.g., electrocardiogram, photoplethysmogram, arterial pressure) with experience in one or more of the following:
 - o instrumentation for acquiring physiologic signals;
 - o computational methods and software tools for analysis of physiologic signals;
 - o construction and/or use of multiparameter physiologic signal and clinical datasets for design and evaluation of patient monitoring algorithms (e.g., for tracking/detecting/predicting disease);
 - computational models and simulations of physiologic waveforms for testing patient monitoring algorithms.

The positions involve laboratory, computational, and/or clinical research, and policy or consulting support for reviews of new medical devices and analysis of device failures. The successful candidate will generate written technical and scientific documents for peer-reviewed publications and consulting support activities. Excellent speaking and writing skills in English are required.

Educational Requirements: Applicants must possess a Ph.D. or equivalent degree in engineering or a related scientific



field. The applicant must be able to demonstrate mastery of principles and practices in Patient Monitoring and Biomedical Engineering. This will enable the staff fellow to serve as a technical authority in the scientific analysis of the safety and effectiveness of medical devices; provide an authoritative analysis of scientific data submitted to the Agency; and develop new and innovative approaches to scientific testing required for medical device reviews by FDA. Applicants who have completed part or all their education outside the US must have their foreign education evaluated by an accredited organization to ensure that the foreign education is comparable to education received in accredited educational institutions in the US. This evaluation must also be provided by midnight Eastern Time on the closing date of this vacancy announcement. For more information on Foreign Education verification, visit the U.S. Department of Education. Another listing of services that can perform this evaluation is available at the National Association of Credential Evaluation Services (NACES) website.

Qualifications: Please document knowledge, skills, and abilities relevant to each area described below:

- Ph.D. from an accredited university in engineering, computer science or a relevant health science field.
- At least three years of experience planning and conducting either 1) clinical research related to the use of wearable sensors for measurement of human movement and/or physiologic signals or 2) computational, laboratory, and/or clinical research related to physiologic signal processing and machine learning in patient monitoring. Demonstration of a track record of independent work is required.
- Experience reviewing, analyzing, and using scientific data or other information to advance and convey understanding of medical devices including verification of wearable sensors used to derive digital biomarkers and digital biomarker validation and/or evaluation of patient monitoring algorithms and systems. Knowledge of the scientific principles and practices associated with designing and evaluating wearable sensors, patient monitoring systems, machine learning algorithms for processing physiologic signals, and/or developing and validating clinical biomarkers.
- Demonstrated ability to participate in and contribute to multi-disciplinary teams and work groups to resolve difficult or controversial research questions.
- Excellent scientific writing and communication skills.

How to Apply: Prior to applying, please see the following instructions:

- Documents to submit: electronic resume or curriculum vitae, cover letter describing why you are uniquely qualified for this, and copy of transcripts
- Compile all applicant documents into one combined document (i.e., Adobe PDF)
- Include Job Reference code "2020-OSEL-DBP-034" in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.

Additional Announcement Information

- 1. Security and Background Requirements: All candidates must meet applicable security requirements which include a background check and a minimum of 3 out of the past 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.
- **2. Benefits:** The Federal Government offers a comprehensive benefits package. Explore the major benefits offered to most Federal employees at https://www.usa.gov/benefits-for-federal-employees
- **3.** For more information about Office of Science and Engineering Laboratories (OSEL) at FDA/CDRH: https://www.fda.gov/about-fda/cdrh-offices/office-science-and-engineering-laboratories.
- **4.** Travel, transportation and relocation expenses will **not** be paid.