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

Staff Fellow (Research Scientist/Engineer)

INTRODUCTION: The Center for Devices and Radiological Health (CDRH or Center), the medical device scientific and regulatory arm of the U.S. Food and Drug Administration (FDA), welcomes applications from Scientists and Engineers, for our Staff Fellow (Research Scientist/Engineer) position in the Office of Science and Engineering Laboratories (OSEL). This position is located in the Division of Biomedical Physics (DBP or Division). DBP fulfills 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 seeking a senior level scientific and regulatory expert and investigator to serve as a technical expert and advisor to the Division Directors for the Neurology Regulatory Science Program. This is a high priority and highly visible Program in OSEL and addresses key focus areas on advancing regulatory science for novel neurodiagnostics, neurointerventional, neuromodulation, and/ or neurostimulation devices. This Program delivers regulatory science tools facilitating device innovation and creates consistency in device test methods where existing standards and guidances do not exist. You will be responsible for providing strategic, technical, and programmatic leadership, and exercise sound scientific and evidenced-based technical judgment in all areas of neurology, including the development of novel methods and knowledge that will be used by other researchers, regulatory reviewers, and medical device manufacturers.

DUTIES/RESPONSIBILITIES: As a DBP Research Scientist/Engineer, you will perform the following duties:

- Serve as the primary investigator in areas of neurology regulatory research, including, but not limited to the development of regulatory science tools for neurodiagnostics, neurointerventional, neuromodulation, or neurostimulation devices.
- Use expert scientific, research, and technical knowledge and vast regulatory expertise to serve as an authoritative and principal advisor to the DBP Directors, as well as serving as an expert resource for the Division, Office, and Center in the areas of neurological devices.
- Provide expert technical consultation to the Office of Product Evaluation and Quality (OPEQ) regarding pre-market medical device and product applications, as well as reported post-market adverse events and concerns associated with central and peripheral nervous systems.
- Provide expert consultation and guidance in the review of neurological devices, including safety, efficacy, and performance, and participate in policy drafting and decisions through the creation and review of FDA guidance documents and consensus standards.
- Analyze and interpret data to identify safety issues related to neurological device use, including local and systemic adverse effects, device malfunction, and sub-optimal effectiveness.
- Contribute significantly to developing the regulatory science strategy for the Neurology Program through contributions in peer-reviewed scientific journals and by leading and participating, regularly, in local and national neuroscience, medical device, standard, and regulatory meetings.
- Forge mutually beneficial formal partnerships with medical device manufacturers, professional scientific organizations, the healthcare community, patient advocacy groups, academia, and other federal, state, and local stakeholders to provide research direction to address specific technical issues, which may influence decisions, Agency guidance, and changes in policy and standards.
- Engage with internal and external stakeholders and stay abreast of new technologies rapidly entering the medical devices markets relevant to neurology.
- Collaborate with colleagues across the Division, Office, and Center to develop of new guidance documents and procedures regarding the regulatory and scientific review of in-scope medical devices

and products.
- Represent the Center and Agency at meetings, discussions, advisory panels, and conferences involving officials from the Department and other Federal, state, and local government agencies, foreign governments, and international agencies, scientific laboratories and institutes involved in biomedical engineering and scientific research, academic and medical communities, and representatives of regulated industry to present and explain DBP research and regulatory activities, plans, policies, and decisions.

PROFESSIONAL EXPERIENCE/KEY REQUIREMENTS: To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which includes the following:
- Must have a minimum of ten (10) years of neuroscience research experience associated with medical devices and products.
- Must have a minimum of five (5) years of experience in developing and leading large-scale, complex neurological research or product development programs utilizing stakeholder input, developing programmatic goals and objectives, budgets, resources, and timelines.
- Technical expertise across neurological medical devices that can help diagnose, prevent, and treat a variety of neurological disorders and conditions such as Alzheimer's disease, Parkinson's disease, major depression, epilepsy, spinal cord injury, and traumatic brain injury.
- Experience leading multidisciplinary scientists in a medical device R&D setting or translational research program resulting in innovative solutions addressing complex issues in neurology or related areas.
- Experience developing external collaborations with medical device industry, academic institutions, and regulatory agencies to drive development of methods, models and processes resulting in high impact solutions.
- Ability to analyze and interpret regulatory guidance to share expertise and advise executive-level leadership on highly complex and precedent setting public health matters.
- Demonstrated success in achieving product development or research goals through effective program management, risk mitigation and resource planning.
- Excellent communication skills.

DESIRED EXPERIENCE/QUALIFICATIONS:
- Applicants with advanced degrees in Biology, Neuroscience, Biomedical Engineering, Chemistry, Physics or related fields.
- Demonstrated success in leading multi-disciplinary teams of scientists and engineers in the development and execution of strategies to address and overcome complex issues.
- Experience in interpreting and presenting complex information and concepts, in both written and oral formats to a broad audience
- Ability to work collaboratively with a diverse cadre of colleagues and stakeholders in a continuous quality improvement ecosystem, as well as prioritize initiatives, work projects, and make critical decisions.

BASIC QUALIFICATIONS: Applicants must meet the specific qualification requirements of the following occupational series: Biologist (0401), Microbiologist (0403), General Physical Science (1301), Health Physics (1306), Physics (1310), Chemist (1320), and Biomedical Engineer (0858)

ADDITIONAL QUALIFCATIONS: 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 her/his 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: **FDA's White Oak Campus** in Silver Spring, Maryland

SALARY: Salary starts at $126,233 and is commensurate with education and post-doctoral experience.

BENEFITS: A comprehensive benefits package is offered to most Federal employees. For additional benefit information click here.

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HOW TO APPLY:

- 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-057"*** in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications and all supporting documentation will be accepted through **December 15, 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.*