

Staff Fellow - Artificial Intelligence/Medical Imaging Device Scientist

INTRODUCTION: The Center for Devices and Radiological Health ([CDRH](#)), the medical devices scientific and regulatory arm of the U.S. Food and Drug Administration ([FDA](#)), welcomes applications from scientists and engineers to join the Office of Science and Engineering Laboratories ([OSEL](#)), as a Staff Fellow, in the Division of Imaging, Diagnostics, and Software Reliability ([DIDSR or Division](#)). This Division develops methods for evaluating the image quality of emerging imaging systems, develops methodologies for characterizing new medical image display devices, evaluates the dose reduction potential of new image reconstruction methods, and assesses the performance of artificial intelligence (AI) and machine learning (ML) algorithms.

POSITION SUMMARY: DIDSR is recruiting Staff Fellows to lead the Division's regulatory science efforts in the development and assessment of advanced diagnostics and medical imaging devices. The Staff Fellows will participate in the regulatory review of medical devices based on emerging technologies. Regulatory science areas of immediate interest are: (1) Evaluation methodologies for monitoring of AI device performance drift in real-world, post-market settings, (2) Methodologies for the regulatory assessment of AI equity: Tools and methods for collecting and analyzing subpopulation-level performance in pre and post-market settings, (3) Physics of magnetic resonance (MR) and applications in deep-learning reconstruction, and (4) Imaging devices for point-of-care and home-use digital health applications (including medical ultrasound applications and skin lesion computer analyzers). These efforts contribute to the regulatory science around emerging AI/ML techniques in medical devices and prepares the Agency for the regulatory evaluation of related products.

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:

- Ph.D. from an accredited university in Engineering, Physics, Optics, Mathematics, Statistics, Computer Science or related scientific fields.
- Experience in theoretical, computational, and experimental aspects of imaging devices.
- Ability to contribute to multi-disciplinary teams to resolve challenging research questions
- Experience reviewing, analyzing, and using scientific data or other information to evaluate the safety, effectiveness, precision, and reliability medical imaging devices.
- Ability to effectively interpret, assess, and communicate, both in oral and written formats, to a variety of audiences (e.g., scientific, management, policy makers) complex scientific information, methodology, and conclusions of scientific and technical analyses.
- Ability to draft decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, and reliability concerns.
- 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 Engineering \(0801\)](#), [Materials Engineering \(0806\)](#), [Mechanical Engineering \(0830\)](#), [Electrical Engineering \(0850\)](#), [Electronics Engineering \(0855\)](#), [Bioengineering and Biomedical Engineering \(0858\)](#), [Computer Engineering \(0854\)](#), [Computer Science \(1550\)](#), [Physics \(1310\)](#), [Mathematics \(1520\)](#), [Mathematical Statistics \(1529\)](#), [Statistics \(1530\)](#)

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 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 range is \$89,834.00 - \$164,102.00 and 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-DIDSR-AIMID_051 - 053**" in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.

- Applications and all supporting documentation will be accepted through **November 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.