



Staff Fellow - Engineering Researcher, Microfluidic Devices (DAM)

INTRODUCTION: The Center for Devices and Radiological Health ([CDRH](#)), a major regulatory component of the Food and Drug Administration ([FDA](#)) and the Department of Health and Human Services, is inviting applications for a Staff Fellow (Engineering Researcher, Microfluidic Devices) in the Division of Applied Mechanics ([DAM](#)), Office of Science and Engineering Laboratories ([OSEL](#)). The division identifies and uses applied mechanics to investigate interactions between the human body and medical devices or radiation-emitting products.

POSITION SUMMARY: DAM is recruiting a Staff Fellow to develop standardized test methods for characterizing the performance of microfluidics-based medical devices. In this position, the Staff Fellow will be an integral part of a team conducting cutting-edge regulatory science that directly impacts public health and promotes medical device safety and innovation. The outcome of the Staff Fellow's work will be shared with stakeholders via publications, regulatory science tools, Medical Device Development Tools (MDDTs), standards, and FDA Guidance documents.

DUTIES / RESPONSIBILITIES: The Staff Fellow will perform the following duties:

- Perform laboratory research to develop standardized test methods that will help to translate early microfluidic systems to finalized clinical use products.
- Lead laboratory projects to assess the performance, safety, and efficacy of microfluidic technologies during their pre-clinical and post-market stages.
- Develop original research projects that advance the science around microfluidic devices, and effectively communicate the research findings through conferences, meetings, publications, and workshops.
- Provide subject matter expertise and regulatory support in the form of consulting reviews of new medical devices and accompanying test reports.
- Formulate clear and concise technical documents for peer-reviewed publications and consulting support activities.
- Utilize expert scientific and technical knowledge to serve as an advisor or consultant on policies involving complex and high-priority matters affecting the regulation of microfluidic-based devices.

PROFESSIONAL EXPERIENCE / KEY REQUIREMENTS: To qualify for this position, the Staff Fellow must demonstrate in their resume the necessary experience, which is equivalent to the following:

- Experience in the following areas is preferred: COVID-19 diagnostics, assay development, diagnostic cartridges, microfluidic device fabrication, biological assays, and at-home diagnostics.
- An understanding of microfluidic materials and manufacturing processes, including chip bonding, interconnections, allowable tolerances, and multiplex systems is preferred.
- Strong fundamentals in fluid mechanics, image analysis using fluorescence and confocal microscopy, computer aided design (CAD), cell counting/tracking, computational fluid dynamics (CFD), hemocompatibility, and fluid-surface interactions are required.
- Real-world experience with animal or clinical studies, and biological sample preparation/handling, would be beneficial.
- Proven expertise in evaluating hemodynamics, microthrombus formation, cell culturing, micro-physiological systems or tissues-on-chip should be highlighted.
- Being proactive, an innovative thinker, organized, and well-prepared are desirable attributes.



- Demonstrate an ability and eagerness to work both independently and collaboratively with multi-disciplinary teams to address difficult or controversial research questions in microfluidics.
- Excellent written and oral communication skills are required.

BASIC QUALIFICATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: [General Engineering \(0801\)](#); [Materials Engineering \(0806\)](#); [Mechanical Engineering \(0830\)](#); [Bioengineering and Biomedical Engineering \(0858\)](#); [Chemical Engineering \(0893\)](#); [Electrical Engineering \(0850\)](#); [Microbiology \(0403\)](#).

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).*

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.
- Prohibited financial interest restrictions may apply. For additional information, please visit the [FDA Ethics and Integrity Office](#).

LOCATIONS: [FDA's White Oak Campus](#) in Silver Spring, Maryland

SALARY: Salary is commensurate with education and experience.

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 **“Staff Fellow - Engineering Researcher, Microfluidic Devices (DAM)”** in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications and all supporting documentation will be accepted through **March 31, 2023**.
- Visit [CDRH Jobs](#) to see additional opportunities.

HHS/FDA is an equal opportunity and affirmative action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or protected veteran status.

