U.S. FOOD & DRUG ADMINISTRATION

Staff Fellow (Engineering Researcher, Cardiovascular Devices)

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, Cardiovascular 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 Staff Fellow to develop standardized test methods for characterizing the mechanical performance of a variety of cardiovascular devices such as blood pumps, heart valves, ventricular assist devices, endovascular stents and grafts. 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 staff fellow's work will be shared with stakeholders via publications, regulatory science tools, Medical Device Development Tools (MDDT), standards, and Guidance documents

DUTIES / RESPONSIBILITIES: As a Staff Fellow, you will perform the following duties:

- Perform laboratory research to develop standardized test methods for characterizing the mechanical performance of a variety of cardiovascular devices such as blood pumps, heart valves, ventricular assist devices, endovascular stents and grafts
- Develop original research projects that advance science surrounding cardiovascular devices, and promote 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.
- 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 or consultant on regulations and policies involving complex and high priority matters affecting the regulation of cardiovascular devices.

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:

- Proven expertise in vitro blood flow evaluation of cardiovascular devices, flow visualization techniques, particle image velocimetry, pressure-flow characterization of medical devices, hemodynamics, turbulence, non-Newtonian flows, computational fluid dynamics, and finite element analysis.
- Ability to understand and evaluate sufficiency of hemodynamics and hemocompatibility (hemolysis and thrombosis) test methods in cardiovascular medical devices
- Ability to participate in and contribute to multi-disciplinary teams and work groups to resolve difficult or controversial research questions.
- Demonstrated independent and collaborative experience leading, planning, and conducting hemodynamics research of cardiovascular medical devices

BASIC QUALIFCATIONS: 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)

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*).

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 ***"CDRH-OSEL-DAM- M5-038 "*** in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications and all supporting documentation will be accepted through **July 15, 2022**.
- 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.

U.S. Food & Drug Administration
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