



Announcement Number: CDRH-OSEL-DAM-2020-7

Position Title: Staff Fellow – Thrombogenicity Evaluation

Salary Range: \$83,398 - \$108,422 (depending upon education and experience)

Open Period: November 8, 2019 – December 8, 2019 Note: The position is open immediately and the applications are reviewed on a rolling basis.

Position Information: Full-Time – Excepted Service Time-Limited to 3 years. After completion of the first 3 years, the appointment has the potential to be extended in 3-year increments, if appropriate.

Duty Location: Silver Spring, MD

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

Job Summary: The Cardiovascular Program within the Division of Applied Mechanics (DAM) in the FDA Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Laboratories (OSEL) has an open full-time staff fellow position to study the hemocompatibility of blood-contacting medical devices. In this position, the staff fellow will be an integral part of a team conducting world-class regulatory science that directly impacts public health and promotes medical device innovation. Specifically, the primary duties for this position will be to perform laboratory research to develop standardized thrombogenicity test methods to characterize platelet activation, thrombosis, and thrombo-embolization caused by medical devices. The staff fellow will also gain extensive experience in the regulatory process and provide regulatory support in the form of consult reviews of new medical devices submissions and analysis of device failures. The candidate should have hands-on hemocompatibility-related research experience of medical materials and devices (e.g., hemolysis, platelet activation/ thrombosis/ embolization, coagulation). Experience in the following research areas/techniques is desirable: optical and electronic microscopy, enzyme-linked immunosorbent assays (ELISA), flow cytometry, hemodynamics, particle image velocimetry (PIV), and computational fluid dynamics (CFD). Excellent speaking and writing skills are required.

Educational Requirements: Applicants must possess a Ph.D. or equivalent degree in biomedical engineering or a relevant scientific field. The applicant must be able to demonstrate mastery of principles and practices in hemocompatibility evaluation of medical devices, hemodynamics, 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, develop new and innovative approaches to scientific testing required for medical device reviews by FDA, and provide an authoritative analysis of scientific data submitted to FDA. Applicants who have completed part or all of 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:

- Extensive experience in hands-on hemocompatibility related research (e.g., hemolysis, platelet activation/thrombosis/ embolization, coagulation) of materials and/or devices. Demonstration of a track record of independent and collaborative research work is required.
- Experience in reviewing, analyzing, and using scientific data or other information to advance and convey understanding of biomedical materials, processes, and medical devices.
- Knowledge of the scientific principles associated with medical device hemodynamics.
- Ability to participate in and contribute to multi-disciplinary teams and work groups to resolve difficult or controversial research questions.
- A Ph.D. from an accredited university in biomedical engineering or a relevant scientific field.
- Excellent written and spoken English.

How to Apply: To apply for this announcement, applicants should provide a complete application package to that includes the following:

- a cover letter with compensation requirements,
- curriculum vitae,
- two to three most relevant journal papers,
- response, not to exceed one page total, to the six knowledge, skills, and abilities from the qualifications section and,
- the names and contact information of three references.

Note: All supporting documents should include the announcement number.

Applications should be sent via email to oselrecruitment@fda.hhs.gov or mailed to the attention of Valerie McRae, FDA/CDRH/OSEL, 10903 New Hampshire Avenue, Building 62, Room 4206, Silver Spring, MD 20993-0002. Applications must be received by closing date to be considered. Electronic submission of application materials is encouraged. Applications sent via e-mail must be submitted as MS Word, or Adobe pdf documents.

Contact Valerie McRae for Questions: Valerie.McRae@fda.hhs.gov

Additional Announcement Information

1. Security and Background Requirements: 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>