



Fellowship Title: ORISE (post-BS, grad student) Fellowship/Summer Internship – Biomedical Engineering Researcher, Sterility and Infection Control

ORISE Fellowship Summary: The Sterility and Infection Control Program within the FDA’s Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Laboratories (OSEL), Division of Biology, Chemistry and Materials Science (DBCMS) has an open position for an ORISE Fellow in Silver Spring, MD. In this position, the ORISE 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. Specifically, the primary duties for this position will be to perform laboratory research to develop standardized test methods to validate medical device drying after reprocessing, sterilant vapor diffusion through materials, and biofilm growth. The outcome of the ORISE fellow’s work will be shared with stakeholders via publications, presentations, regulatory science tools, standards, and FDA Guidance Documents. The fellow will also gain experience in the regulatory review processes used by FDA to assess safety and efficacy of new and existing medical devices by attending internal working group discussions with regulatory personnel. The candidate should have research experience in the development of *in vitro* experimental techniques, such as designing and executing experimental procedures (e.g., Standard Operating Procedures) and designing and troubleshooting apparatus/flow loop setup. This may include participation in protocol development to validate medical device drying after reprocessing, sterilant vapor diffusion through materials, and biofilm growth. The candidate will assist with test apparatus construction and operation, as well as method development and data collection/analysis. A background in sterilization technologies and reprocessing procedures is desirable. Excellent speaking and writing skills in English are required.

Educational Requirements: Applicants must possess a BS, MS, Ph.D. or equivalent degree in biomedical engineering, mechanical engineering, materials science, or a relevant scientific field. The applicant must be able to demonstrate mastery of principles and practices in fluid mechanics, biomechanics, and/or mechanical engineering. This will enable the fellow to develop new and innovative approaches to scientific testing in the determination of safety and effectiveness of new medical devices. Applicants who have completed part or all of their education outside the U.S. must have their foreign education evaluated by an accredited organization to ensure the foreign education is comparable to education received in accredited educational institutions in the U.S. 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:

- For PhD./M.S. candidates, at least 3 years of experience during their education that included leading, planning, and conducting research. Ideally the candidate should have experience with medical devices. Demonstration of a track record of independent and collaborative research work is required.
- Experience with *in vitro* flow evaluation, such as development of flow models, flow visualization techniques, particle image velocimetry, and pressure-flow characterization of medical devices.
- Ability to participate in and contribute to multi-disciplinary teams and work groups to resolve difficult or controversial research questions.
- A degree (BS, MS, PhD) from an accredited university in biomedical engineering, mechanical engineering, or a relevant scientific field.
- Excellent written and spoken English.

How to Apply: To apply for this announcement, applicants should provide a curriculum vitae via email to Jon.Weeks@fda.hhs.gov. Electronic submission of application materials is encouraged. Applications sent via e-mail must be submitted as MS Word or Adobe pdf documents.