Position Title: Microbiologist
Announcement Number: CDRH-OSEL-DBCMS-20170039
Open Period: 11/21/2016 to 1/31/2017

Department of Health and Human Services (DHHS)/US Food and Drug Administration (USFDA)
Center for Devices and Radiological Health (CDRH)
Office of Science and Engineering Laboratories (OSEL)
Division of Biology, Chemistry and Materials Science (DBCMS)

POSITION REQUIREMENTS: An established leader in the area of microbiology, this position is responsible for evaluating the safety and performance of medical devices and radiological products.

This position is located in one of the operating divisions of the Office of Science and Engineering Laboratories (OSEL) in the Center for Devices and Radiological Health (CDRH). The Office is responsible for planning, conducting, supporting, and evaluating research on the safety performance, and quality of medical devices and for providing biological and engineering information and risk assessments required for compliance actions, performance standards development, and other regulatory and educational programs. Principal functions of this position include research and development in microbiology and infection control, leadership of a broad and diverse laboratory program, and regulatory review of medical devices with the goal to promote and protect the public health.

This is a Research Microbiologist position (salary range from $108,887 - $160,300).

DUTIES AND RESPONSIBILITIES:

The research microbiologist designs and conducts experiments to identify, measure and characterize microorganisms and their products that may influence infections associated with devices using extensive knowledge of microbiology, chemistry, biochemistry, genetics, and physics, and the development of the methods, procedures, and techniques involved to troubleshoot and modify the protocols for assessing the causes of infections associated with devices.

The research microbiologist also designs and conducts experiments to evaluate the effectiveness of cleaning, disinfection and sterilization of medical devices. The research microbiologist analyzes the experimental data to determine the efficacy of chemical disinfectants and sterilants to prevent infections associated with reusable devices used in the clinical settings.

The research microbiologist:
• conducts applied research on infections associated with devices; including determining the quantitative endpoints for cleaning reusable medical devices that will be used on different clinical applications and patients, validation of test methods for chemical sterilization, and the effects of new materials on efficacy of disinfectants used for the device.
• collaborates with other research centers within and outside of the FDA.
• provides leadership of a broad and diverse laboratory program.
• provides critical consulting evaluations of pre-market submissions as well as post-market actions, evaluations, and safety communications.
• provides materials used in the development of the Center’s standards and guidelines.
• provides consulting and laboratory support for the activities for other offices in the Center.
• performs activities to support the development of guidelines, standards, new technological approaches to regulatory problems and to maintain the state-of-the-art expertise in order to provide high-quality consulting services to the Center and to other Federal agencies.
• participates in duties and responsibilities that are not research in nature, such as serve on committees on the interagency task group regarding chemical sterilization and disinfectants, cleaning validation studies for reprocessing of reusable devices, and other federal agencies advising on reprocessing single-use and reusable medical devices, and sterility quality assessment of reviews by Office of Device Evaluation (ODE) and Office of Compliance (OC).

At the national levels, the research microbiologist represents the Agency and at the international levels he/she is regarded as a subject matter expert and represents the U.S. during the development of standards (AAMI, ASTM, and ISO). Because the research microbiologist is involved in the development of standards for the Center, requests will come not only from inside the Agency, but also from the general public, industry, and international regulatory stakeholders. Prompt response to any request for information or clarification of standards requires that expert knowledge is essential.

The research microbiologist serves as an educator and mentor by presenting seminars and posters, and data from the local Agency level to national and international meetings and to academia, participating and lecturing in courses and educational activities serving as mentor to faculty and students. The research microbiologist also acts as a writer and editor by reviewing colleagues manuscripts for publication, publishing his/her own research finding in highly regarded science journals, reviewing and writing national and international standards, guidance documents, recalls, health hazard evaluations, warning letters, safety communications, and public health notifications as appropriate. The research microbiologist also acts as a reviewer of several scientific peer-reviewed journals.

Within the regulatory science context, the approximate percentage of time devoted to research
and regulatory activities: 50% research and 50% regulatory activities.

**REGULATORY SCIENCE ACTIVITIES:**

**Research:**

Under the broad supervision of the Director of Biology, Chemistry and Materials Sciences, the microbiologist will plan, develop and conduct highly specialized research. He/she will direct independent research projects as they relate to the Division’s and Center’s overall mission on regulatory science, with particular emphasis on mechanisms involved in the area of infection control by assessing the causes of infections associated with the use of medical devices. He/she will possess and maintain critical knowledge needed to regulate the safety and efficacy of cleaning and disinfection/sterilization of new and reusable devices prior to use on the next patient or user. Particular attention will be made to develop test methods for evaluating cleaning and sterilization of devices and medical equipment, how the device design and materials influence the effectiveness of cleaning, disinfection/sterilization. This research should be relevant to the understanding of validating cleaning procedures, aseptic use of devices, the role of materials and device design on cleaning, sterilization/disinfection of devices. The information derived from this research may be used in improving the design (and/or re-design) of current and future innovative devices.

The research microbiologist will provide guidance and collaborate with other scientists on the development and implementation of the techniques described above and will also:

- Assist in training members of the laboratory of new techniques and methodologies
- Analyze data, interpret results, and prepare manuscripts based on laboratory findings
- Prepare and present laboratory findings within the Center and at national/international conferences
- Critically review manuscripts for other scientists within the Center and for the editorial boards of scientific journals
- Read scientific papers related to areas of research and regulatory expertise to maintain current knowledge of research and development.
- Seek funding for research operations from internal and external sources.

**Regulatory Review:**

The research microbiologist will also serve as key product consultant reviewer for issues related to sterility (e.g. bioburden and bacterial endotoxin testing, cleaning, sterilization, and disinfection, and biofilm research) of devices. He/she will serve as the FDA representative on Expert Scientific Groups organized to discuss and resolve issues related to infections associated with devices and for reviewing FDA guidelines for the biosafety of the FDA research laboratories. The research microbiologist will direct research aimed at identifying test methods that will more reliably identify those factors which may allow infections to be associated with
devices. Information from these studies will be used to formulate recommendations for Agency reviewers and compliance inspectors, and for sponsors as to what assays/test and methods as well as device design should be performed when cleaning and sterilizing/disinfecting both new and reusable medical devices with regard to infections associated with the use of these devices.

QUALIFICATIONS: Qualification requirements in the vacancy announcements are based on the U.S. Office of Personnel Management (OPM) Qualification Standards Handbook, which contains federal qualification standards. This handbook is available on the Office of Personnel Management's website located at: http://www.opm.gov/qualifications.

BASIC REQUIREMENTS: This position requires applicants to meet a Basic Education Requirement in addition to at least one year of specialized experience or a substitution of education for experience in order to be found minimally qualified. You MUST meet one of the following basic education requirements:

A. Degree: microbiology; or biology, chemistry, or basic medical science that included at least 20 semester hours in microbiology and other subjects related to the study of microorganisms, and 20 semester hours in the physical and mathematical sciences combining course work in organic chemistry or biochemistry, physics, and college algebra, or their equivalent.

AND/OR

B. Combination of education and experience: courses equivalent to a major in microbiology, biology, chemistry, or basic medical science that included courses as shown in A above, plus appropriate experience or additional education.

Specialized experience:

To qualify for this position, you MUST demonstrate experience and knowledge in the following:

- Demonstrate leadership in a laboratory research program and team in microbiology or related scientific discipline;
- Oversee lab functions for staff performing analysis of medical products and bi-products and microbiological and biochemical hazards using traditional microbiological methods and molecular analytical techniques;
- Review lab processes to ensure that proper microbiological lab processes are followed; ensure results meet lab standards and to recommend improvements; and
- Ensure the lab is current on microbiological methods for medical product safety and lab staff is properly trained to ensure quality work products.
- Understand and apply basic and advanced microbiology techniques including bacteriophage propagation and plaque assay, biofilm characterization research, multi-drug resistant microorganisms.
• Participate in standards organizations such as but not limited to AAMI, ASTM, and ISO.
• Demonstrate experience in establishing laboratory protocols/guidances, manufacturing practices, and/or clinical protocols for sterilization and infection control.

OR

**EDUCATION:** A Ph.D. or equivalent graduate degree or three years of graduate education leading to such a degree with a major study in microbiology, or specific area of study such as bacteriology, virology, immunology, microbial genetics; or specific applied fields of microbiology such as clinical and public health microbiology. Graduate study in related fields such as experimental pathology, infectious diseases, epidemiology, and biochemistry may also be pertinent, provided it has direct application to microbiological work. Other required experience: leadership of a laboratory research team; basic and advanced microbiology techniques including bacteriophage propagation and plaque assay, knowledge of biofilm formation and characterization, knowledge on multi-drug resistant microorganisms; participation and leadership positions in standards organizations such as but not limited to AAMI, ASTM, and ISO; experience in establishing laboratory protocols/guidances, manufacturing practices, and/or clinical protocols for sterilization and infection control; and serving as a mentor for junior scientists in his/her field of expertise.

**How to Apply:** To apply for this announcement, applicants must provide a complete application package which includes: (a) a cover letter with compensation requirements, (b) curriculum vitae, (c) responses to the knowledge, general and specialized experience, and skills from the Qualifications section, and (d) the names and contact information of three references. 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 4229, Silver Spring, MD 20993-0002. Applications must be received by closing date in order to be considered. Electronic submission of application materials is encouraged. Applications sent via e-mail must be submitted as MS Word, or Adobe pdf. **Note: All supporting documents should include the announcement number.**

For more information about the position and application process: [http://www.fda.gov/MedicalDevices/ScienceandResearch/ucm211173.htm](http://www.fda.gov/MedicalDevices/ScienceandResearch/ucm211173.htm)

Contact Information for specific questions to Ms. Chirelle Taylor @ Chirelle.Taylor@fda.hhs.gov

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