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Opportunity Title: FDA Fellowship in Sterility and Infection Control
Opportunity Reference Code: FDA-CDRH-2022-15

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDRH-2022-15

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Cover Letter (upload to Writing area)
- One educational or professional recommendation

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDRH@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 12/31/2022 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

A research opportunity is available in the Division of Biology, Chemistry and Materials Science (DBCMS) within the Office of Science and Engineering Labs (OSEL) at the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

The Sterility and Infection Control Program is searching for 4 candidates to assist with the development of regulatory science tools to help our stakeholders facilitate the clearance of medical devices.

1. Computational Scientist - PhD
The objective of the research project is to develop a computational model that will help to predict gaseous sterilization processes. This project will include helping to identify cold spots within the chamber so that manufacturers can utilize appropriate sterilization procedures with reduced empirical testing. The participant will assist with computational modeling, model validation, analyzing data, and interpreting results.

2. Chemist/Materials Scientist - MS
The objective of the research project is to develop a multi-dimensional risk assessment tool to aid manufacturers in the switch from one sterilant to another. The project will include analyzing device and packaging compatibility with various sterilants, reviewing extractable and leachable compounds from various materials under different sterilization conditions, and ultimately providing a tool that will recommend if additional testing is necessary to determine safety and efficacy with the alternative sterilant. The participant will assist with performing experiments, analyzing data, and interpreting results.

3. Analytical Chemist - PhD
The objective of the research project is to advance anti-microbial technologies as they relate to biofilm associated medical device related infections. The project will include developing methods of detection of biofilms on medical devices, methods for reproducible biofilm formation on devices, and methods for assessing effectiveness of antimicrobials to prevent biofouling. The participant will assist with method development and implementation, performing experiments, analyzing data, and interpreting results. The participant is expected to be familiar with sample preparation for MALDI-TOF MS based proteomics including protein extraction, digestion and peptide purification from complex biological samples including cells, tissues, and body fluids for proteomics experiments and targeted MS approaches. A good understanding of data analysis such as mass fingerprinting, PTM analysis, biological annotation, and data interpretation tools to simplify the identification of proteins in complex biological samples is desirable.

4. Chemist - BS
The objective of the research project is to establish validation criteria for determining cleaning and drying efficacy during reprocessing of medical devices. The project will include developing test methods and appropriate endpoints to evaluate dryness to ensure sterilization during reuse of medical equipment. The participant will assist with performing experiments, analyzing data, and interpreting results.

• These opportunities are on-site for laboratory research at the FDA campus.
• Compensation is commensurate with education and experience.
• The estimated appointment term is one year depending on the availability of funding.
• Applications will be reviewed on a rolling-basis. Open Until Filled.

Learning objective: As a result of their research participation, the participants will gain experience conducting research toward developing regulatory science tools specific to their discipline.

Anticipated Appointment Start Date: August 1, 2022; start date is flexible

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This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time on-site for laboratory research at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management (OPM) is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total

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of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate should be currently pursuing or have received a bachelor's, master's, or doctoral degree in a relevant field (e.g., biology, microbiology, biochemistry, chemistry, computer science), with completion by August 1, 2022. Degree must have been received within the past five years.

Preferred skills:

- Computational Scientist: Experience with computational modeling of gaseous entities and an understanding of terminal sterilization processes of medical devices
- Chemist/Materials Scientist: Experience with analysis of medical device materials compatibility with terminal sterilization processes and development of risk assessment methodology
- Analytical Chemist: Experience in developing analytical methods (MALDI-TOF), performing chemical characterization, and an understanding of bacterial biofilms
- Chemist: Experience in chemical techniques to evaluate residual moisture detection after reprocessing of medical devices and an understanding of sterilization of medical devices

Must meet security requirements including a minimum of 3 out of the past 5 years with residency status in the US.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or anticipated to be received by 8/1/2022 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (3 👁)
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Engineering** (3 👁)
  - **Life Health and Medical Sciences** (9 👁)

Affirmation

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)