Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Science and Engineering Laboratories (OSEL)

Position(s): Senior Science Advisor

Location(s): Silver Spring, Maryland, FDA headquarters, White Oak Campus

Travel Requirements: This position may require up to 25% travel.

Application Period: Thursday, August 26, 2021, through Thursday, September 30, 2021

Salary: Salary starts at $144,128.00 and is commensurate with experience

Conditions of Employment: U.S. Citizenship or permanent U.S. residency is required

Special Notes: This position is being filled under an excepted hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of the authority. Additional information on 21st Century Cures Act can be found here.

Introduction: The Center for Devices and Radiological Health (CDRH or Center) assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Within CDRH, the Office of Science and Engineering Laboratories (OSEL), which is comprised of multidisciplinary scientists and engineers from a wide array of specializations, works to advance the mission of CDRH by promoting innovation, through experimentation and research to support the development of new and emerging life-saving and life-sustaining medical devices. Additionally, OSEL utilizes and openly shares its data, technical expertise, and regulatory knowledge with internal and external stakeholders across the Agency, the Department of Health and Human Services, academia, industry, and standards organizations to ensure the availability of timely, comprehensive, and accurate medical device information throughout the total product lifecycle to support and ensure evidenced-based and transparent regulatory decision making.

Position Summary: CDRH is seeking an experienced, innovative, and team-oriented Computer Modeling and Simulation (CM & S) expert who is dedicated to improving the health outcomes and the quality of life of patients through the advancement of therapeutic and diagnostic medical devices and products. In this role, you will report to and also serve as the Senior Science Advisor to the Director of OSEL. Your critical work and technical expertise will directly impact the 20 research programs in OSEL and the scientific reviews and regulatory decision-making of each medical product Office across the Center. As the Senior Science Advisor, you will serve as a vital member of

CDRH's expert scientific, technical, and regulatory community. Further, as a luminary in the field, you will serve as an expert liaison for OSEL and interface with the medical device industry and other components of the FDA, the Department of Health and Human Services, as well as the scientific, standards, patient, and health care communities. If you are looking for a position to help accelerate medical device innovation to directly and positively impact the lives of patients and their families, we encourage you to apply.

Duties/Responsibilities: As the OSEL Senior Science Advisor and CM&S expert, you will:

- Collaborate with colleagues across the Office, Center, and Agency to develop new guidance documents, policies, and standards regarding the use of CM&S tools in the review of medical devices, diagnostic equipment, and combination products, regulated by the Center, in the pre-market phase of the Total Product Life Cycle.
- Be responsible for the coordination, management, and advancement of OSEL's CM&S Program, to include providing expert guidance, advice, recommendations to Office, Center, and Agency leadership, as well other internal and external stakeholders.
- Advise OSEL senior leadership on a full range of regulatory science developments involving laboratory support concerns involving partnerships with other organizations on the implementation of the Office's broad regulatory science policies that support the mission of CDRH.
- Collaborate with the OSEL Director and other Center executive leaders to drive the uniform adoption, implementation, and consistent application of new CM&S practices into the current regulatory review process of medical devices.
- As an expert on CM&S tools, you will serve as CDRH's liaison and encourage consensus amongst regulatory reviewers, the scientific community, and the MedTech industry to utilize CM&S tools in the precompetitive space of the regulatory review process.
- Drive the effort to reduce industry's administrative burden, continuously streamline technology, supporting product development, and facilitating innovation, without compromising the regulatory review process.
- Conduct independent studies and evaluate industry submitted data applying CM&S policies and protocols to support Office and Center leadership in evidenced-based regulatory decisions making regarding medical devices, combination products, and diagnostic equipment within scope.
- Serve as an expert consultant and liaison on cross-functional teams within the Office, Center, and Agency related to the development, utilization, and interpretation of CM&S tools.
- Collaborate with colleagues across OSEL and the Offices of Health Technology (OHT 1 - 7) to develop and establish new guidance documents, policies, and best practices to support alternative methodologies in conducting pre-market reviews of medical products.

Professional Experience/Key Requirements:

To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which includes the following:

- Experience in computer modeling and simulation design, medical device design, clinical trial evaluation and re-engineering, and reliability testing.
- Experience in leading multidisciplinary scientists, clinicians, and other regulatory professionals in large-scale science-based organizations.
- Ability to analyze and interpret regulatory policy and guidance to share expertise and advise leadership on highly complex and precedent setting public health matters.

- Leads the strategic achievement of organizational goals, evaluating organizational performance and taking action to improve performance.

Desirable Education:

- Applicants with advanced degrees in engineering, biomedical engineering, computer engineering, systems engineering, physics, computer science, or related field.
- Prior experience in a scientific, regulatory, or medical device manufacturing setting.
- Ability to work collaboratively with a diverse cadre of colleagues and stakeholders in a continuous quality improvement ecosystem.

Basic Qualifications:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Conditions of Employment:

- A probationary period may be required.
- Background and/or Security investigation required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption.
- This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. For additional information on the prohibited financial interests, visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply: Submit an electronic resume or curriculum vitae, cover letter containing a brief summary of scientific accomplishments, SF-50 (if applicable), and a copy of unofficial transcripts all in one document (**Adobe PDF**) to CDRHRecruitment@fda.hhs.gov, with Job Reference code ***"2020-OSEL- IO-009"*** in the subject line. Applications will be accepted through **September 30, 2021.**

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor.

- Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation Policy

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits.

Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when:

- An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job.
- An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace.
- An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events.

You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis.

Learn more about disability employment and reasonable accommodations or how to contact an agency.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

FDA is an equal opportunity employer