Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)
Office of Clinical Evidence and Analysis (OCEA)
Division of Clinical Evidence and Analysis II (DCEA2)

Position(s): Deputy Division Director (Supervisory Data Scientist)

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

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

Application Period: Thursday, May 19, 2022, through Thursday, June 16, 2022

Salary: Salary starts at $148,484.00 and is commensurate with experience

Conditions of Employment: United States Citizenship 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. The Office of Product Evaluation and Quality (OPEQ or Office) 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.

The Office of Clinical Evidence and Analysis (OCEA or Office), within OPEQ, provides policy and programmatic support for clinical trials, the protection of human subjects, biostatistics, real-world evidence, epidemiological analysis and outreach, and collaborates with hospitals, health systems, industry, and other external stakeholders. Additionally, OCEA provides regulatory oversight of medical device clinical investigations, to ensure good laboratory practices and clinical practices in support of premarket review. Further, OCEA oversees the application of modern artificial intelligence (AI) tools, including machine learning (ML) algorithms and deep learning methodologies that can be evaluated, piloted, and implemented at scale, by CDRH, to identify or predict medical device safety signals faster and earlier in the life cycle of devices.

Position Summary: OCEA is seeking an innovative scientific, technical, and regulatory expert to serve as Deputy Division Director in the Division of Clinical Analysis II (DCEA2). The Division develops, implements, and promotes innovative statistical methodology in the design and analysis of

clinical evidence generated throughout the Total Product Life Cycle of medical devices. In this position, you will report to the OCEA Deputy Office Director and serve as the authoritative voice on analytical, statistical, and programmatic techniques to collect, organize, analyze, and interpret unique and highly specialized data sets related to the pre-market review, compliance assessment, and post-market surveillance of medical devices and products. You will lead the Office's efforts of advancing statistical science for the Center by prioritizing new data analytic tools, adopting cutting-edge methodologies, and incorporating AI and ML in the analysis of clinical evidence and statistical data to improve decision-making. Further, you will manage, provide technical leadership, and support an interdisciplinary team of scientific experts charged with evaluating the consistency and validity of industry reported information, as well as conducting real-world data assessments of medical device usage, and evaluate reported data from both the clinical and scientific communities, related to the safety, efficacy, and reliability of medical devices and products.

Supervisory Responsibilities: You will assist the DCEA2 Director in setting strategy, advancing initiatives, and ensuring the goals, priorities, and objectives of the Division align with those of OCEA, OPEQ, and the Center. As a creative and collaborative leader, you will assist in managing and growing a high-performing, interdisciplinary scientific, technical, and professional team, for optimal efficiency and performance, in support of advancing the strategic vision of the Office. As such, you will evaluate the technical and managerial performance of your subordinate supervisors and devote at least 25 percent of your time towards coaching, mentoring, and supervising your leadership team.

Duties/Responsibilities: As the DCEA2 Deputy Division Director, you will:

- Serve as the resident expert and cogent voice to the OCEA Deputy Office Director on matters involving the adoption and implementation of new and cutting-edge data analytic tools for the review of complex medical device data sets encompassing the total product life cycle.
- Provide expert consultation to Office leadership on programmatic plans, the healthcare and scientific communities, and industry related trends, significant concerns, and adverse event reported data regarding medical devices.
- Provide technical expertise to product teams in the development, implementation and oversight of new technologies in the field of Data Science.
- Collaborate with the DCEA 2 Division Director and the OCEA Deputy Office Director in the planning, organizing, and the establishment or realignment of priorities, assignments, and work projects to advance new initiatives and/or the programmatic and regulatory objectives of the Division and Office.
- Represent the Division and Office at meetings, advisory panels, and conferences involving officials from the Department and other Federal, state, and local government agencies, foreign governments and international agencies, the scientific, academic, and medical communities, and representatives of regulated industry to share OCEA's activities, plans, policies, and decisions.
- Advise the Division Director and Office leadership on the utilization of new and emerging technologies associated with AI and ML in the analysis of medical device data to detect early signals, trends, and other critical information.
- Draft decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, and reliability concerns.
- Forge mutually beneficial formal partnerships with medical device manufacturers, foreign agencies, professional scientific organizations, health care community, patient advocacy groups, academia, and other federal, state, and local stakeholders.
- Create and sustains a strong and dynamic culture within the Division including organizational agility, a focus on continuous improvement, and staff empowerment and collaboration.

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

- Experience in leading and managing interdisciplinary 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.
- Leading the strategic achievement of organizational goals, evaluating organizational performance, and taking action to improve outcomes.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Skillful in effectively interpreting and presenting complex scientific, technical, and regulatory information and concepts, in both written and oral formats, for a variety of audiences.

Desirable Education and Experience:

- Applicants with advanced degrees in Biomedical Engineering, Computer Engineering, Electrical Engineering, General Engineering, Systems Engineering, Computer Science, Mathematics, Mathematical Statistics, Statistics, or related fields.
- 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, and a copy of unofficial transcripts all in one document (**Adobe PDF**) to CDRHRecruitment@fda.hhs.gov, with Job Reference code ***"2020-OCEA-DCEA2-MDE-018"*** in the subject line. Applications will be accepted through **June 16, 2022.**

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.

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