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)

Position(s): Division Director

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

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

Application Period: Tuesday, November 29, 2022, through Thursday, December 15, 2022

Salary: Salary starts at $168,914.00 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), as the scientific and regulatory component of the U.S. Food and Drug Administration (FDA) charged with facilitating and ensuring medical device innovation, safety, and effectiveness, and advancing regulatory science is now accepting applications from exceptionally qualified candidates to serve as a Division Director in the Office of Clinical Evidence and Analysis (OCEA or Office). This Office, within the Office of Product Evaluation and Quality (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 tools, including machine learning and deep learning methodologies, that can be evaluated, piloted, and implemented at scale by CDRH to help the Center evaluate clinical evidence and other device-related data to more efficiently conduct regulatory review activities in support of the Center's mission.

Position Summary: OCEA is seeking a regulatory science leader to serve as the Director of the Division of Clinical Evidence and Analysis III (DCEA3). DCEA3, referred to as the Division of Clinical Science and Outreach, is responsible for epidemiological and real-world evidence infrastructure development, epidemiologic study design, methodology, and data analysis, as well as outreach and collaboration with external stakeholders. The Director will oversee the development and implementation of innovative methodologies in the design of studies and the analysis of associated clinical evidence generated throughout the Total Product Life Cycle of medical devices

and radiation-emitting products.

Supervisory Responsibilities: You will assist the OCEA Deputy Office 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 Division Director of DCEA3, the selected candidate will:

- Serve as a nationally recognized expert and authoritative voice in epidemiologic study design, methodologies, and analytical and programming techniques necessary to collect, organize, analyze, and interpret unique and highly specialized data sets.
- Directs the design, development, coordination, implementation, and management of complex public health epidemiological studies and surveillance systems to ensure programmatic and project goals and objectives are consistent, compatible, and complementary with mission of the Office and Center.
- Directs and measures the effects and quality of all aspects of activities under FDA's national Medical Product Safety Network, MedSun, and incorporates the clinical community's perspective into the regulatory and patient-safety work of FDA.
- Draft recommendations, most of which will be technical in nature, to describe real-world evidence activities, analysis, results, and conclusions to assist in regulatory decision-making.
- Coordinate with stakeholders on the development of infrastructure novel methodology for generating real-world evidence.
- Direct the epidemiologic analysis and interpretation for real-world studies.
- Ensure the safety of marketed devices through overseeing the development of methods for post-market surveillance and conduct of real-world evidence based post-market safety studies.
- Communicate data findings to Office leadership stakeholders using different visual formats and graphic displays to share meaningful presentations of data and provide reports.
- As the Center's, subject matter expert, you will keep abreast of innovative approaches to epidemiologic study design techniques, methodology, and analysis.
- 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 sustain a strong and dynamic culture within the Division including organizational agility, a focus on continuous improvement, and staff empowerment and collaboration.
- Provide subject matter expertise and regulatory support in the form of consultation in the reviews of new medical devices and accompanying test data and reports.

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

- Experience in leading and managing interdisciplinary scientists, clinicians, and other regulatory professionals in large-scale science-based organizations.
- Experience in evaluating, developing, and re-engineering real-world evidence studies, as well as developing, applying, and validating assessment tools, endpoints, and methodologies.

- 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, General Engineering, Systems Engineering, Epidemiology, Data Science, 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-DCEA3-Director"*** in the subject line. Applications will be accepted through **December 15, 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.

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