U.S. FOOD & DRUG ADMINISTRATION

TITLE 21 VACANCY ANNOUNCEMENT

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): Associate Director (Epidemiologist)

Series: The position of Associate Director may be filled by candidates from the following occupational series: General Health Scientist/Epidemiologist (0601), General Mathematics and Statistics (1501), Mathematical Statistician (1529), and Statistician (1530),

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

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

Application Period: Monday, October 18, 2021, through Friday, November 5, 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 Product Evaluation and Quality (OPEQ or Super Office) is responsible for setting strategy and overseeing the Offices of Health Technology 1-7, Office of Clinical Evidence & Analysis (OCEA or Office), Office of Regulatory Programs (ORP). Using a focused Total Product Lifecycle approach, the Office ensures quality end-to-end device evaluation, and the consistent interpretation and application of regulatory policy and guidance. The Office ensures that these activities are aligned to the overall strategy and priorities of CDRH and FDA and contains staff responsible for Clinical Affairs, Quality Management and Analysis, and Strategic Initiatives.

OPEQ's OCEA 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 offers biostatistical and epidemiologic analyses, as well as the support in the development of data infrastructure and expertise for clinical investigations and real-world evidence.

Position Summary: CDRH is seeking an experienced, public health focused, and team-oriented Associated Director who is dedicated to improving the health outcomes of patients through innovation, evidence-based decision making, clinical/patient outcome data, and the advancement of therapeutic and diagnostic medical devices. As a luminary in the field of Epidemiology, serving as an Associate Director, you will report to the OCEA Office Director and serve as the trusted advisor focused on real-world evidence (RWE) infrastructure formation for the total product lifecycle of medical devices and radiation emitting diagnostic equipment regulated by the Center. In this critical role, you will be charged with providing expert analysis and evaluation of clinical studies submitted by industry to include design, methodology, endpoints, and conclusions. Additionally, you will evaluate the consistency and validity of industry reported information, as well as conduct 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 in scope medical products.

Duties/Responsibilities: As the Associate Director, you will:

- Utilize your expertise to develop and implement epidemiological analysis plans to evaluate clinical study data related to the therapeutic and diagnostic benefits of medical devices, diagnostic equipment, and combination products, based on intended use.
- Serve as the authoritative voice on public health surveillance and epidemiological studies and collaborate with colleagues across the Office, Super Office, Center, and Agency to lead the development of guidance documents, policies, and standards regarding the use of epidemiological studies, design, methodology, patient assessment tools, and endpoints in the evaluation of medical devices, diagnostic equipment, and combination products.
- Offer expert guidance and feedback to Office staff on medical device product reviews, to include clinical evidence and RWE focused activities and programs.
- Utilize your subject matters expertise to provide oversight of the integration of in-depth data science knowledge into analytics and visualization tools that will be utilized 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 patient-based studies, in particular assessment tool determination, endpoint development, data validation, and patient elicitation methods.
- As the Center's, subject matter expert, you will keep abreast of innovative approaches to clinical study design techniques, methodology, and biostatistics.
- 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.
- Represent Office, the Super Office, and Center at industry, standards, and FDA advisory panel meetings to share expert position regarding study design, assessment tools, endpoints, and data collected related to real-world evidence use of medical devices, combination products, and diagnostic equipment.
- Provide epidemiologic oversight to OCEA-led analyses and interpretation of findings from RWE

studies, highlighting areas of significant concern to the OCEA Office Director.
- Offers expert advice to Office, Super Office, and Center leadership on programmatic plans, health care community, scientific, and industry related trends, significant concerns, and adverse event reported data regarding medical products regulated by the Center.
- Draft recommendations, most of which will be technical in nature, to describe data science activities, analysis, results, and conclusions to assist in regulatory decision-making.

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 evaluating, developing, and re-engineering clinical studies, as well as developing, applying, and validating assessment tools, endpoints, and methodologies.
- Evidence of a strong commitment to data quality, validation, and transparency.
- 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.
- Ability to understand and interpret scientific methods and information and communicate the data to both scientific and lay audiences, in written and presentation formats
- Strong skills in using statistical tools and database software, as well as proficiency in collating and analyzing epidemiologic data

Desirable Education:
Applicants with advanced degrees in Epidemiology, Biostatistics, Mathematical Statistics, and General Mathematics and Statistics.

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 ***"2017-OCEA- IO-M4 -RWE-52"*** in the subject line. Applications will be accepted through

November 5, 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