# 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 & Analysis (OCEA)
# Division of Clinical Evidence and Analysis 3 (DCEA3)

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**Position:** Deputy Division Director, OPEQ/OCEA/DCEA3

**Series:** The position of Deputy Division Director may be filled by candidates from the following occupational series: Data Scientist (301), Physician (0602), Biologist (0401), Microbiologist (0403), General Health Scientist (0601), Consumer Safety Officer (0696), General Engineer (0801), Material Engineer (0806), Electronics Engineer (0855), Biomedical Engineer (0858), Chemist (1320) Mechanical Engineer (0830), Electrical Engineer (0850), Mathematical Statistician (1529), Statistician (1530)

**Location(s):** Remote Eligible

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

**Application Period**: Friday, March 3, 2023, through Friday, March 31, 2023

**Salary:** Salary starts at $155,700.00 and is commensurate with experience.

**Conditions of Employment:** U.S. 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 Deputy Director of the Division of Clinical Evidence & Analysis 3 (DCEA 3) 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.

**Position Summary**: OCEA is seeking a regulatory science leader to serve as a Deputy Director of DCEA 3, also referred to as the Division of Clinical Science and Outreach. DCEA3 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 including hospitals and clinical researchers. As the Deputy Division Director, the incumbent serves under the direction of the DCEA3 Director, regarding matters of general policy, program objectives and priorities, project resource allocations, and budget limitations.

You will assist the DCEA 3 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 Division. 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 a Deputy Division Director of DCEA3, the selected candidate will support the DCEA 3 Director in efforts to:

- Direct 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.
- Direct and measure the effects and quality of all aspects of activities under FDA's national Medical Product Safety Network, MedSun, and incorporate the clinical community's perspective into the regulatory and patient-safety work of FDA.
- 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.

**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.
- 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.

**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 supervisory 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.
- Due to COVID-19, the Agency is currently in an expanded telework posture. If selected, you may be expected to temporarily telework, even if your home is located outside the local commuting area. Once employees are permitted to return to the office, you will be expected to report to the duty station listed on this announcement within 45 days. At that time, you may be eligible to request to continue to telework one or more days a pay period depending upon the terms of the agency's telework policy. As required by Executive Order 14043, Federal executive branch employees are required to be fully vaccinated against COVID-19 regardless of the employee's duty location or work arrangement (e.g., telework, remote work, etc.), subject to such exceptions as required by law. If selected, you will be required to be vaccinated against COVID-19 and will receive instructions on how to provide documentation.

**How to Apply:** Submit an electronic resume or curriculum vitae, a 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 ***"2023-OCEA-DCEA3-Deputy Division Director"*** in the subject line. Applications will be accepted through **March 31, 2023.**

**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 factors.

- 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*