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)
Division of Clinical Evidence & Analysis (DCEA)

Position: Deputy Division Director (Supervisory Interdisciplinary Scientist)

Series: The position of Deputy Division Director (Supervisory Interdisciplinary Scientist) may be filled by candidates from the following occupational series: Biologist (0401), Microbiologist (0403), General Health Scientist/Epidemiologist (0601), Physician (0602), Consumer Safety Officer (0696), General Engineer (0801), Electrical Engineer (0850), Biomedical Engineer (0858) and Medical Officer (0602).

Location(s): Silver Spring, Maryland

Travel Requirements: This position requires occasional travel.

Application Period: Tuesday October 20, 2020 through Tuesday October 17, 2020

Salary: Salary is commensurate with education and 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) 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 the 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) is responsible for setting strategy and overseeing the Offices of Health Technology 1-7, Office of Clinical Evidence & Analysis (OCEA), Office of Regulatory Programs (ORP), Quality & Analytics Staff, Clinical & Scientific Policy Staff, Strategic Initiatives Staff, Regulation Policy & Guidance Staff, and Operations Staff. 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.

Within the Office of Product Evaluation & Quality, is the Office of Evidence & Analysis, which provides policy and program support regarding clinical trials, biostatistics, real-world evidence, epidemiological analysis and outreach and collaborates with hospitals and other external stakeholders. In the Office, the Division of Clinical Evidence and Analysis 1 is responsible for the policy and program support regarding clinical trial design and conduct, epidemiological and real-world evidence analyses, and outreach and collaboration with external stakeholders.

Position Summary:
The Deputy Division Director, reporting directly to the Division Director, partners in providing technical leadership and exercises scientific judgment in regulating various medical products.

Supervisory Responsibilities:
Exercises significant responsibilities in dealing with officials of other units or organizations, or in advising management officials of higher rank.

Plans work to be accomplished by subordinates, sets and adjusts short-term priorities, and prepares schedules for completion of work; assigns work to subordinates based on priorities, selective consideration of the difficulty and requirements of assignments, and the capabilities of employees.

Coach and mentor staff and help sustain a strong and dynamic culture across teams in the Division, including organizational agility, staff empowerment and mobility, and collaboration.

Duties/Responsibilities:
The Deputy Division Director performs the following duties:

- Develops policy and provides programmatic support across clinical evidence areas (such as clinical investigations, bioresearch compliance, human subject protection, clinical evidence synthesis and analysis, epidemiological methodologies and data infrastructure, and collaboration and outreach with hospitals) for device specific offices engaged in Total Product Lifecycle review of devices.
- Provides the Assistant Directors and other Division personnel technical expertise, scientific and engineering judgment, and is a recognized authority in the regulation of various medical products across the total product life cycle, including premarket, compliance, and post-market evaluation of medical products.
- Provides regulatory oversight of medical device clinical investigations, good laboratory practice (GLP), and good clinical practice (GCP) issues in support of pre-market activities and post-market studies.
- Develops policies, strategies, and plans to address cross-cutting population health issues.
- Identifies, evaluates, and resolves broad problems in areas that will typically change, modify, and create new scientific and regulatory policies, procedures, and methods.

- Utilizes expertise on clinical investigations and assessments regarding the relevance and reliability of real-world data sources and evidence.
- Oversees outreach and collaborations with hospitals and external stakeholders.
- Develops policy, procedures, and guidance, and coordinates handling of complex cases and activities with national public health impact.
- Develops and implements policies that contribute to successful execution of medical device clinical studies.
- Provides information and consultation to individuals, federal agencies, private industries (medical device), universities, and/or foreign governments on scientific and public health issues.
- Represents the FDA/CDRH at national scientific conferences, multiple stakeholder committees, registry steering committees, national working groups, and/or FDA advisory panel meetings.

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.

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

- Directing, overseeing, and managing a multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with medical products (i.e. devices, biologicals, drugs, etc.);
- Performing and leading data quality assessments, data management and analysis efforts for real-world data sources (including electronic health records (EHR), hospital and pharmacy claims data, mobile health data, registries, or patient reported outcomes);
- Representing the organization on committees and at professional meetings, and conducting outreach to relevant stakeholder populations; and
- Leading strategic achievement of organizational goals, evaluating performance, and taking action to improve performance.

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

Desirable Qualifications/Experience:
Applicants with an advanced degree in science, engineering, or medical fields are highly desired.

- Prior clinical and/or regulatory experience with medical products.
- Excellent oral and written communication skills.
- Ability to work collaboratively with a diverse cadre of customers and healthcare stakeholders.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.

Additional Conditions of Employment:

- One-year 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, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply:
Prior to applying, please see the following instructions:

- Documents to submit: electronic resume or curriculum vitae, cover letter containing

a brief summary of scientific accomplishments, and copy of transcripts

- Compile all applicant documents into **one combined document (i.e. Adobe PDF)**
- Include Job Reference code ***"OCEA-DCEA1-2020-LKI-03"*** in the email subject line.
- Email comprehensive applicant package/document to CDRHRecruitment@fda.hhs.gov by **Tuesday, October 17, 2020**.

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

FDA is an equal opportunity employer.