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)
Division of Clinical Evidence and Analysis 2-Biostatistics (DCEA2)

Open to U.S. Citizens.

Position: Division Director

Series: This position is interdisciplinary in nature may be filled by candidates from the following occupational series: Mathematical Statistician (1529) and Statistician (1530).

Location(s): Silver Spring, Maryland

Travel Requirements: This position requires up to 25% travel.

Application Period: Wednesday, March 17, 2021 through Friday, April 16, 2021

Area of Consideration: FDA employees.

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.

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 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). 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.

CDRH's Office of Clinical Evidence and Evaluation (OCEA) provides policy and program support regarding clinical trials, biostatistics, real-world evidence, epidemiological analysis and outreach and collaboration with hospitals and other external stakeholders. They also provide policy and program support for clinical evidence and human subject protection in addition to regulatory oversight of medical device clinical investigations, good laboratory practice (GLP), and good clinical practice (GCP) issues in support of premarket review and provide biostatistical and epidemiologic analyses, as well as support in the development of data infrastructure and expertise on clinical investigations and real-world evidence.

The Division of Biostatistics or Clinical Evidence and Analysis 2 (DCEA2), within OCEA, is recognized for developing, implementing, and promoting innovative statistical methodology in the design and analysis of clinical evidence generated throughout the total product life cycle of medical devices. DCEA2 ensures the safety and effectiveness of medical devices through their statistical review of regulatory submissions. In addition, the division supports CDRH's regulatory mission by advancing statistical science and promoting the adoption of least burdensome, cutting edge methodologies through original research, peer-reviewed publications, and training. This research spans clinical trial design, Bayesian statistics, causal inference, meta-analysis, signal detection, real world data analysis, and risk-score based methods for site inspection.

Position Summary:
Partnering with the Office Director, the Director, Division of Clinical Evidence & Analysis 2 (DCEA) provides executive leadership and exercises biostatistics judgment and activities in the area of both therapeutic and diagnostic devices. Reviews critical materials submitted to or generated by Center including IDE, PMA, 510K applications, standards and guidelines for statistical validity and consistency. Oversees the original statistical research and modeling studies and collaborations on the design, analysis, and interpretation of laboratory, clinical, and epidemiologic studies on the health effects of medical device use. Supervises the comprehensive statistical computational support programs in the division conducted internally and externally to the Center including collaborative design, analysis, and participation in the standards and compliance activities.

Duties/Responsibilities:
Duties may include but are not limited to:

Performs risk assessments and risk/benefit analyses for medical devices and participates with other Center components in regulatory, and educational activities. Collaborates with statisticians in other Centers and Agencies on matters of mutual interest including methodological issues and statistical research. Interacts with national, international, public and private organizations to identify common statistical problems and areas of mutual interest associated with the regulation of medical devices.

The Director ensures activities are aligned to the goals and priorities of DCEA2. Ensures DCEA2 advances the OPEQ's mission and vision. Implements OPEQ and OCEA's Strategic Priorities. Develops and implements policies and plans that are sound and feasible in relation to OCEA, OPEQ and Center goals and federal budgetary and economic realities. Signs off on complex work products as needed on behalf of the Division Director. Serves as a technical expert and advisor and is recognized as an authority and leader in DCEA2 functions.

Serves as a technical expert and resource for the purpose of providing expertise, direction, and feedback to managers and staff on policies and program support within one or more regulatory program areas. Incumbent oversees the quality of scientific and regulatory reviews across the total product lifecycle for products assigned to the Division, including premarket evaluation, postmarket evaluation, compliance, and surveillance. As a technical and scientific expert on products overseeing the Division management team, provides guidance and feedback to managers and staff on product reviews and other medical or radiological health product-specific activities and programs.

The Director works with members of the Division and Office management team, to leverage the necessary expertise on premarket, compliance, and surveillance, as well as clinical, scientific, and regulatory policy expertise for reviews. They provide oversight and direction for biostatistical reviews and decisions on regulatory submissions including IDE, PMA, 510K applications, standards and guidelines for statistical validity and consistency and all supplements and amendments to these submissions.

Professional Experience/Key Requirements:
To qualify for this position, you must possess experience and expertise including:

- Senior level supervisory experience, which demonstrates strong leadership abilities;
- Experience using statistical software to manipulate and analyze data;
- Proven ability to advance and innovate statistical methodology for medical products;
- Experience developing and applying statistical algorithms to big data sets; and
- Experience in overseeing review of and providing recommendations on regulatory submissions.

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 Experience:

- Ability to prioritize and to make critical decisions.
- Excellent communication skills.
- Ability to work collaboratively with a diverse cadre of customers and stakeholders.
- Ability to build effective teams.
- Advanced degree in statistics, biostatistics, or mathematics is preferred.

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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.

Conditions of Employment:

- One-year supervisory probationary period may be required.
- Background and/or Security investigation required.
- U.S. citizenship is required.

- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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:

Submit electronic resume or curriculum vitae, letter of interest, SF-50, and a copy of unofficial transcripts to CDRHRecruitment@fda.hhs.gov with ***"DCEA2 Division Director"*** in the subject line. Applications will be accepted through **April 16, 2021**.

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

FDA is an equal opportunity employer.