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 Health Technology 7 (OHT7)
Division of Chemistry and Toxicology Devices (DCTD)

Position: Assistant Director (Supervisory Interdisciplinary Scientist)

Series: The position of Supervisory Interdisciplinary Scientist may be filled by candidates from the following occupational series: Regulatory Counsel (301), Biologist (0401), Microbiologist (0403), General Health Scientist/Epidemiologist (0601), Nurse (610), Consumer Safety Officer (0696), Physical Scientist (1301), Physicist (1310), Chemist (1320), General Engineer (0801), Material Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858), Mathematical Statistician (1529), and Statistician (1530).

Location(s): Silver Spring, Maryland

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

Application Period: Wednesday, April 7, 2021, through Thursday, April 15, 2021

Salary: Salary starts at $122,530 and 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 Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

The mission of the Center for Devices and Radiological Health (CDRH or Center) is to protect and promote the public health by performing essential public health tasks designed to ensure medical devices, diagnostic products, and radiological equipment, to include new and emerging technologies, are safe, reliable, and effective for the American people. Within CDRH, the Office of Product Evaluation and Quality (OPEQ or Office) is responsible for ensuring 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 recruits and hires scientific, clinical, and administrative

professionals responsible for Clinical Affairs, Quality Management and Analysis, and Strategic Initiatives. The Office of Health Technology 7 (OHT7), which is one of the seven OPEQ Offices, is responsible for the in vitro diagnostic, radiological health, and mammography quality standards programs. The Division of Chemistry and Toxicology Devices (DCTD or Division) serves as the primary source for scientific and medical expertise regarding the safety and efficacy of diabetes medical products throughout the total product lifecycle.

Position Summary:
CDRH is seeking an experienced scientific and regulatory professional to serve as the Assistant Director of the Diabetes Diagnostic Devices Branch within DCTD. In this critical supervisory position, you will report directly to Deputy Division Director and will be responsible for providing expert leadership, administrative management, and exercising sound scientific, clinical, and evidenced-based technical judgement in the review of medical devices associated with the diagnosis, treatment, and management of diabetes throughout the total product lifecycle.

Supervisory Responsibilities:
As a creative and collaborative leader, you will manage and grow a high-performing, multidisciplinary scientific, technical, and professional team in support of advancing the strategic vision of the Division and Office. As such, you will evaluate the technical performance of your team members who serve as experts in their respective fields and devote at least 25 percent of your time towards coaching, mentoring, and supervising your employees.

Duties/Responsibilities:
As the Assistant Director you will performs the following:

- Utilize expert scientific and technical knowledge and vast regulatory expertise to serve as an authoritative advisor for DCTD and OPEQ on diabetes diagnostic medical devices, both novel and existing, encompassing the entire product lifecycle.
- Provide expert consultation to Division and Office leadership on programmatic plans, health care community, scientific, and industry related trends, significant concerns, and adverse event reported data regarding diabetes diagnostic medical devices regulated within the Division.
- Collaborate in the development, coordination, and implementation of policies and programmatic norms rooted in science to assure medical products, especially those novel in nature and with emerging technologies, within scope are safe, effective, reliable, and available for patients and providers.
- Collaborates with team members, colleagues and Division leadership to ensure uniform adoption, implementation, and consistent application of OPEQ and Division-wide guidance, initiatives, and policies regarding regulatory oversight of medical devices within the scope of DCTD.
- Draft decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, and reliability concerns.
- Represent the Division and Office at scientific, international standard organization, and other professional meetings, conferences, stakeholder meetings, working groups, and FDA advisory panels.
- Ensure the uniformed high quality and consistency of scientific and regulatory reviews across the total product lifecycle for diabetes diagnostic medical devices assigned to the Division.
- Partner with members of DCTD's and OPEQ's Senior Leadership Team, as appropriate, to leverage the necessary expertise on pre-market, compliance, and surveillance, as well as clinical, scientific, and regulatory policy expertise for reviews.

- Collaborates with Division leadership to plan, organize, and establish or realign priorities, assignments, and work projects to advance new initiatives and/or the programmatic and regulatory objectives of the Division and Office
- Provide comprehensive support to product advisory panels, industry, and consultants and coordinates actions on classification actions, petitions, premarket notifications (510(k)s), premarket approval applications (PMAs), PDPs, De Novos, 513(g)s, and Investigational Device Exemptions (IDEs) with Center and Agency components or other organizations, when appropriate.

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:

- Manage and lead a multidisciplinary staff responsible for scientific, regulatory, and/or public health activities associated with FDA regulated medical devices;
- Analyze, interpret, and share regulatory policy expertise with review team and advise Division and Office leadership on scientific matters that may be highly complex, precedent setting, or controversial in nature;
- Draft decision or recommendation memoranda based on regulations, established policy, and current guidance regarding medical devices;
- Represent DCTD, as an expert at Agency, professional associations, international standards, industry, advisory committee, and stakeholder meetings.

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

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.

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.

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 ***"2020-OPEQ-OHT7-DCTD-LKI-01"*** in the subject line. Applications will be accepted through **April 15, 2021**.

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

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