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 3 (OHT3)
Division of Health Technology (DHT)

Position: Assistant Director, Human Factors and Reliability Engineering Team (Supervisory Interdisciplinary Scientist)

Series: The position of Supervisory Interdisciplinary Scientist may be filled by candidates from the following occupational series: Physician (0602); Regulatory Counsel (301); Biologist (0401); Microbiologist (0403); General Health Scientist/Epidemiologist (0601); Nurse Consultant (610); Consumer Safety Officer (0696); General Engineer (0801); Material Engineer (0806); Mechanical Engineer (0830); Electrical Engineer (0850); Biomedical Engineer (0858); Physical Scientist (1301); Physicist (1310); Chemist (1320); Mathematical Statistician (1529); and Statistician (1530).

Location(s): Silver Spring, Maryland

Travel Requirements: This position requires occasional travel.

Application Period: Tuesday December 8, 2020 through Monday January 4, 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 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 CDRH is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States. Within CDRH, the Office of Product Evaluation and Quality (OPEQ), Office of Health Technology 3 is responsible for the total lifecycle (TPLC) review of reproductive, gastro-renal, urological and general hospital devices. We are also responsible for the CDRH Human Factors program. The

Division of Health Technology (DHT3C): Division of Drug Delivery and General Hospital Devices, and Human Factors is responsible for the total lifecycle (TPLC) review of drug delivery and general hospital devices and the OPEQ human factors program.

Position Summary:
Reporting directly to an OPEQ Division Director, the Assistant Director provides technical leadership on human factors/usability topics and exercises scientific and engineering judgment in regulating various medical products. Judgment and technical skill are applied across the total product lifecycle including premarket, compliance/enforcement, and postmarket safety issues including the evaluation of complex issues concerning sophisticated devices and highly controversial issues.

The Assistant Director will develop and lead the strategic development and growth of the CDRH Human Factors program. The position includes oversight of CDRH pre- and post-market device review of human factors data.

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 Assistant Director performs the following:

- Oversee the consistent application of human factors-related policy, regulatory guidance, analysis, interpretation, and programmatic support provided by teams within the division to other parts of the Office, OPEQ, and CDRH to ensure timely, accurate, and high-quality work products.
- Serve as a technical expert and resource for the team(s) for the purpose of providing technical direction and feedback to staff on policies and program support within one or more regulatory program areas.
- Ensure quality and consistency of technical and operational activities conducted within the team.
- Provide signatory authority on novel or complex issues and provides initial supervisory review for work products addressing regulatory policy, process and tools.
- Oversee the quality of human factors consult reviews across the total product lifecycle from across OPEQ, including premarket evaluation, postmarket evaluation, compliance, and surveillance.
- Serve as a technical and scientific expert on human factors within the division management team for the purpose of providing technical guidance and feedback to team staff on reviews and other human factors-specific activities and programs.

- Work with members of the Division and Office management 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.
- Provide technical and non-technical support to product advisory panels, panel members, 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.
- Provides oversight and direction for reviews and decisions on classifications, petitions, 510(k)s, HDEs, PMAs, PDPs, IDEs, De Novos and 513(g)s and all supplements and amendments to these submissions.

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:

- Developing and recommending approaches for complex situations using federal policies, procedures and regulations (e.g. the Federal Food, Drug and Cosmetic Act);
- Leading activities/programs that include advising on or developing human factors-related policy/guidance for medical device and radiological health products or combination products in an industry, healthcare, academic or government 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

Desirable Education:
Applicants with an advanced degree in science, engineering, or medical fields are highly desired. Additionally, candidates should demonstrate that they have:

- Excellent leadership and communication skills.
- Ability to work collaboratively with a diverse cadre of customers and 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 ***"2021-OPEQ-IO-M4-P-039"*** in the email subject line.
- Email comprehensive applicant package/document to CDRHRecruitment@fda.hhs.gov by **Monday January 4, 2020**.

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

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