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 Regulatory Programs (ORP)

Position: Assistant Director – Division of Regulatory Programs I

Series: The position of may be filled by candidates from the following occupational series: Biologist (0401), General Health Scientist/Epidemiologist (0601), Consumer Safety Officer (0696), and General Engineer (0801)

Location(s): Silver Spring, Maryland, FDA headquarters, White Oak Campus

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

Application Period: Tuesday, January 4, 2022, through Monday, January 17, 2022

Salary: Salary starts at $122,530.00 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 Center for Devices and Radiological Health (CDRH or Center) 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.

The Office of Product Evaluation and Quality (OPEQ) assures patients have access to high quality, safe and effective products throughout the total product lifecycle (TPLC) by implementing program areas through which medical devices are evaluated or cleared for clinical investigations and marketing.

The Office of Regulatory Programs (ORP or Office), within OPEQ, provides support across a variety of premarket, post-market, and compliance programs impacting the regulated medical device industry. This Office performs cross-cutting analysis to assess the performance of programs, develops tools that aid in evaluating the safety, performance, and quality of medical devices throughout their TPLC.

Position Summary: ORP is seeking a public health minded team oriented medical device review expert to serve as its Assistant Director of the Medical Device Review Team, within the Division of Regulatory Programs I (DRPI or Division). In this critical position, reporting to the DRPI Director, you will be responsible for planning, leading, and coordinating the end-to-end medical device review support activities in the areas of policy evaluation and interpretation and medical device classification in the pre-market space as well as compliance and enforcement efforts in the post-market space. Your critical regulatory work and the utilization of your expert nurturing managerial expertise will assist the Director in advancing the mission of the Division and Office.

Supervisory Responsibilities:
You will assist the DRPI Director in setting strategy, advancing initiatives, and ensuring the goals, priorities, and objectives of the Division align with those of OPEQ and the Center. As a collaborative leader, you will manage and grow a high-performing, multidisciplinary scientific, technical, and professional team for optimal proficiency and performance. 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 perform the following duties:

- With an intense focus on medical device safety, efficacy, reliability, and performance, you will utilize your vast medical device expertise and policy experience to provide input on regulatory submissions from industry, across the total product lifecycle of medical devices and products regulated by the Center.
- As a subject matter expert, you will collaborate with Division and Office leadership to update or develop new regulations, policies, and protocols to address new regulatory pathways in the TPLC review of novel medical devices and products with emerging technologies.
- Proactively identify and share technology trends and emerging science that may influence and/or reshape medical device decision-making, current policies, protocols, and procedures, medical device development and manufacturing, and the review process.
- Collaborate with inter and intra-Office cross-functional teams to assist in the development of health technology security standards, policies, and procedures related to regulatory review of medical devices and diagnostic equipment to minimize potential threats and to address vulnerabilities of networked, network capable, and mobile medical devices.
- Provide comprehensive support to OPEQ's device specific offices, product advisory panels, industry, and consultants and coordinate activities regarding classification actions, petitions, premarket notifications (510(k)s), premarket approval applications (PMAs), Product Development Protocols, De Novos, 513(g)s, Investigational Device Exemptions (IDEs), Humanitarian Device Exemptions (HDEs) and Pre-submissions (Q-subs).
- Represent the Division, as appropriate, at Office, Center, working group, industry, patient advocacy, health care, standards, scientific, government, and other professional meetings.
- Draft decisions and recommendations of public health significance, which may impact the availability of certain products due to safety, efficacy, performance, and reliability concerns.
- 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 medical devices and products regulated by the Center.

- Collaborate with Division leadership to plan, organize, and establish or realign assignments, priorities, and work projects to advance new initiatives and/or programmatic and regulatory objectives for the Division and Office.
- Engage and collaborate with patient advocacy groups, industry, healthcare, and scientific communities to address all adverse event data and medical concerns associated with medical devices and products regulated by the Center.
- Coordinate classification actions and pre-market review determinations for medical devices regulated by the Center.

Professional Experience/Key Requirements:

To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which includes or is equivalent to the following:

- Experience in leading and managing multidisciplinary scientists, clinicians, public health, and other regulatory professionals in large-scale science-based organizations.
- Ability to analyze, interpret, and share regulatory policy expertise with review teams and offer guidance and advise leadership on highly complex, precedent-setting, or controversial public health matters.
- Experience in leading strategic achievement of organizational goals, evaluating workforce performance, and deploying effective interventions to improve organizational 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:

- Advanced degrees in applied, life, and/or physical sciences, such as Biology, Chemistry, Engineering, Physics, health care disciplines, or related fields are highly desired.
- Prior experience in a scientific, regulatory, or medical device manufacturing setting.
- Ability to work collaboratively with a diverse cadre of colleagues and stakeholders in a continuous quality improvement ecosystem.

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

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-ORP-DRP1-020**"* in the subject line. Applications will be accepted through **January 17, 2022.** Commissioned officers in the United States Public Health Service (PHS) interested in performing the duties of this position may apply to this announcement. Officers must follow the instructions for how to apply and include a copy of their most recent personnel orders in addition to the required documents. If selected, candidates will be referred as

Commissioned Corps (CC) personnel and not as candidates for a Cures appointment

Conditions of Employment:

- A 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.
- 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.

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. 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.