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 Policy (OP)

Position: Regulatory Policy Analyst (OP)

Application Period: 3/6/2023 – 4/6/2023

Location(s): Silver Spring, MD

Salary: Starts at $112,015 and is commensurate with qualifications and experience.

CURES Band(s): Bands C and D

Area of Consideration: U.S. Citizens

Travel Requirements: Up to 25% or less

Work Schedule: Full Time

Bargaining Unit: 8888

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), a major regulatory component of the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS), is inviting applications for a ***Regulatory Policy Analyst*** in the Office of Policy (OP). OP provides leadership for all policy-related activities at CDRH. Reporting directly to the Deputy Director, the ***Regulatory Policy Analyst*** will be responsible for: drafting supporting statements for information collection requests as required per the Paperwork Reduction Act (PRA) for regulations, guidance documents and/or other requests for information (e.g., surveys), and collaborative document development within the center, specifically for medical devices and radiological health products; leading work groups to accomplish these responsibilities and objectives; coordinating with other Centers and Offices within the FDA; and analyzing public comments on such regulatory documents which could have PRA implications and implementing appropriate revisions to documents.

Duties/Responsibilities

The ***Regulatory Policy Analyst*** also performs the following duties:

- Writes supporting statements and required documents for publication in the Federal Register, which can significantly vary in complexity.
- Critically reviews documents related to CDRH policy and program proposals, focused on guidance documents and regulations to ascertain whether new data is being requested or revisions to existing information collection activities are necessary.
- Analyzes existing, revised and/or new program initiatives to estimate the burden to industry and the public for information collections under the PRA.

- Develops, in collaboration with other CDRH offices and divisions and in accordance with CDRH Guiding Principles, PRA Supporting Statements (SS) for new or revised information collection submissions to support complex, high-priority, and cross-cutting matters affecting medical devices and radiological health products.
- For each PRA SS, describes the circumstances necessitating the information collection, the estimated burden (time and cost) under PRA, provides an explanation for the methodology applied and the basis of the estimates, program changes and adjustments used to describe the purpose and use of the collected information, among other requirements under the PRA requirements.
- Uses regulatory knowledge and analytic skills to draft, revise and consolidate comments and discussion in the efficient development of complex supporting statements for guidance and/or cross-cutting regulations that impact multiple CDRH or FDA components.
- Effectively engages with others across the Center or Agency to develop complex SS to support CDRH's requests for information collections included in guidance documents and/or cross-cutting regulations.
- Effectively engages with the Agency to seek input and discuss areas of unresolved matters and cogently integrate concepts into PRA SS in support of guidance documents or regulations, considering the applicable laws and relevant regulatory framework.
- Interpret and analyze existing policies and precedents that affect internal and industry program activities of regulated products in which CDRH has jurisdiction.
- Effectively works with colleagues in analyzing the impact of existing or proposed legislation on PRA implications, which may need to be reflected in burden analyses as part of appropriation requests.
- Analytically reviews public comments received on PRA SS to finalize such documents efficiently and effectively in collaboration with critical stakeholders to support our final policy documents (e.g., guidance, regulations)

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
   a. **Qualified** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
   b. **Outstanding** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

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

- Ability to apply and interpret policies, procedures, regulations and statutory provisions (e.g., Federal Food, Drug and Cosmetic Act, Paperwork Reduction Act).
- Skillful in effectively interpreting and presenting complex information and concepts, in both written and oral formats.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Ability to actively embrace diversity by actively promoting an inclusive workplace that maximizes the talents of each person.
- Ability to focus on objectives and results when considering the various alternatives to a decision.
- Ability to prioritize and make critical decisions.

Basic Qualifications: Candidates must possess the required individual occupational requirements to qualify for the following occupational series: Miscellaneous Administration and Program Series, 0301.

How to Apply

Prior to applying, please see the following instructions:

- Submit an electronic resume or curriculum vitae, a cover letter containing a brief summary of accomplishments and why you're interested in this position.
- Include Job Reference code ***"Regulatory Policy Analyst (OP)"*** in the email subject line.
- Email applicant package to CDRHRecruitment@fda.hhs.gov.
- **Visit CDRH Jobs to see additional opportunities.**

Conditions of Employment

- United States Citizenship is required.
- One-year supervisory 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.

Public Health Services Commissioned Corps Officers

PHS Commissioned Corps Officers interested in performing the duties of this position within the Commissioned Corps may apply to this announcement. Officers must follow the instructions for how to apply and include their most recent orders in addition to the required documents. If selected, candidates will be referred to (CC) personnel and not as candidates for a Cures appointment.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information, please visit the FDA Ethics web

page: 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.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

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