



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-Guidance (OP)

Application Period: 3/30/2023 – 4/27/2023

Location(s): [Silver Spring, MD](#)

Salary: Starts at \$132,368 and is commensurate with qualifications and experience.

CURES Band(s): Bands 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-Guidance** in the Office of Policy ([OP](#)). OP provides leadership for all policy-related activities at CDRH. Reporting directly to the Associate Director of Guidance, Legislation and Special Projects, the **Regulatory Policy Analyst-Guidance** will primarily be responsible for: drafting guidance documents and other policy documents, and collaborative policy development within CDRH, specifically for medical devices and radiological health products; leading work groups to accomplish these responsibilities and objectives; coordinating with other FDA Centers and Offices; analyzing public comments on guidance documents and implementing appropriate revisions; and providing regulatory/policy support regarding the policies and procedures relevant to the development and issuance of CDRH guidance documents.

Duties/Responsibilities

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

- Write and critically review documents related to CDRH policy and program proposals, focused on guidance documents and other policy documents (e.g., discussion papers of public health importance).
- Develop, in collaboration with other CDRH offices and divisions and in accordance with CDRH Guiding Principles, policies and programs involving complex, high-priority, and cross-cutting matters affecting medical devices and radiological health products.

- Apply regulatory knowledge and policy development skills to draft, revise and consolidate comments and discussion in the efficient development of complex guidance and/or cross-cutting policies that impact multiple CDRH or FDA components.
- Lead cross-Center or cross-Agency working groups to develop complex guidance documents and/or cross-cutting policies.
- Effectively brief and engage Senior management to seek input and discuss areas of unresolved policy matters and cogently integrate concepts into guidance documents, considering the applicable laws and relevant regulatory framework.

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:

- Expertise in medical device law, including but not limited to, the Federal Food, Drug, and Cosmetic (FD&C) Act, the Public Health Service Act, the Medical Device User Fees Amendments and subsequent amendments, etc.
- Expert knowledge of FDA’s regulatory and statutory framework to advise leadership of the impact on an organization or industry.
- Ability to analyze and evaluate policy/guidance and determine appropriate approaches regarding the regulation of devices.
- Utilizing regulatory knowledge to draft, revise and consolidate complex and technical information in a clear and concise manner for consideration by internal and external stakeholders.
- Ability to lead working groups and work effectively and collaboratively within diverse teams as well as 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-Guidance (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.