Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Clinical Policy and Programs (OCPP)
Office of Combination Products (OCP)

Application Period: July 14, 2023-August 14, 2023

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Senior Regulatory Counsel

Series: 301

Location(s): Remote

Salary: Starting at $155,700-$219,523

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: N/A

Bargaining Unit: Yes

Relocation Expenses Reimbursement: Not applicable

This position is being filled under a stream-lined 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 this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

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 Office of Clinical Policy and Programs (OCPP) is to advance the public health by developing, leading, and executing programs and cross-cutting initiatives that support FDA's centers in making effective, safe, and innovative medical products available to the American people. OCPP also coordinates and supports patient engagement activities across the medical product centers to foster awareness and collaboration with patients, their

advocates, and the FDA, with the goal to strengthen and modernize key functions to enhance communication to our stakeholders and further elevate the role of patients in our work in medical product development.

The Senior Regulatory Council supports the Director of the Office of Combination Products (OCP) in the planning, development, and implementation of policies and regulations. The Senior Regulatory Council's responsibilities include: supporting the Office's policy program and priorities; review and clearance of guidance, regulations and other policy/regulatory actions conducted by or presented to OCP; ensuring that relevant staff from OCP and other Agency components are engaged in OCP policy/regulatory development efforts; and ensuring the consistent implementation of policy activities with statutory and regulatory requirements.

Duties/Responsibilities

The Senior Regulatory Council initiates, oversees and otherwise participates as appropriate in OCP policy initiatives relating to the full lifecycle of combination products from classification and Center assignment to premarket review and postmarket regulation, including rulemaking and guidance development as well as associated programmatic activities such as design and implementation of procedures, systems, training programs, and monitoring and assessment tools. The Senior Regulatory Council also engages on product-specific matters raising precedential questions or concerning controversial or sensitive issues that have major policy or regulatory implications. These efforts directly affect how these products are regulated by the medical product Centers. These duties and responsibilities arise from and relate closely to the mandates for OCP as clarified and augmented by section 3038 of the 20th Century Cures Act regarding the efficient, consistent, and effective regulation of combination products.

The incumbent routinely collaborates with scientific and regulatory subject matter experts in the Centers, and other Agency components, and attorneys in OCC to develop and ensure the sound implementation of a robust, coherent regulatory program, including by developing and standing up premarket and postmarket regulations, guidance, procedures, trainings, and monitoring and assessing programs and activities. These efforts require a deep understanding of multiple regulatory regimes (e.g., drugs, devices, and biologics) and the ability to develop both substantively appropriate and politically viable solutions, working very closely with senior Center staff.

The incumbent provides input in the development of FDA positions in response to Congressional inquiries and legislative initiatives affecting combination product regulation. The incumbent supports the medical products centers in developing and reviewing their guidance documents and policies that impact combination products and the combined use of medical products. The incumbent also engages with stakeholders, including trade associations, to consider their questions, concerns, and programmatic proposals.

The incumbent researches and develops solutions to the most difficult problems, complex cases, critical issues, and significant or precedent-setting situations related to the regulation of

combination products, including consideration of the interpretation, application and enforcement of agency statutes, regulations, decisions, and guidances.

The incumbent develops and uses an authoritative knowledge of agency goals and objectives, operational activities, and program authorities and responsibilities; content and interpretation of agency statutes, rules, precedents, and decisions. The incumbent provides expert advice, guidance, assistance, interpretations, and recommendations to the OCP director and Agency's senior staff, key management personnel and administrators, , departmental and congressional counterparts, other federal and state and local governmental officials, and others in such areas as: anticipated and emerging responsibilities and authorities under new, proposed, or amended legislation, specific regulatory issues and actions; development and interpretation of agency policies, procedures and regulations to implement new or modified legislative and statutory authorities and program responsibilities.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

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.*

Education Requirement:

301 Series: Experience that equipped the applicant with the particular knowledge, skills, and abilities to perform successfully the duties of the position, and that is typically in or related to the work of the position to be filled. To be creditable, specialized experience must have been equivalent to at least the next lower grade level in the normal line of progression for the occupation in the organization.

Desired Education:
The ideal candidate will possess a Juris Doctorate (J.D.) degree from an accredited institution

Professional Experience:

Knoweldge and experience in interpreting FDA laws, policy, and statutes

Desired Professional Experience:

- Relevant experience either developing and implementing guidances or regulations for a Federal Agency or working for an entity directly involved in combination products
- Demonstrated ability to identify and analyze problems, determine and weigh the relevance and accuracy of related information, evaluate solutions, and make recommendations with supporting rationales.
- Demonstrated ability to communicate well orally and in writing.
- Demonstrated ability to work successfully with staff at all levels of the organization and varying levels of domain expertise, and to collaborate across boundaries to build strategic relationships and achieve common goals.
- Demonstrated ability to work independently and as a contributing collaborative team member.
- Demonstrated ability to organize time effectively, determine priorities, and move work forward efficiently.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university.For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/High Risk

A background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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

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

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.

How to Apply

How to Apply: Submit resume or curriculum vitae with cover letter by COB August 14th to: Jessica Bennett. Candidate resumes may be shared with hiring official within the Office of Clinical Policy and Programs with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions please contact Jessica Bennett. Please reference Job Reference ID: Snr Reg Counsel-OCP

Announcement Contact

For questions regarding this Cures position, please contact Jessica Bennett (Jessica.Bennett@fda.hhs.gov)

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