Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of the Center Director (OCD)
Patient Focused Drug Development (PFDD)

Application Period: December 13, 2021-January 14, 2022

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: Science Policy Analyst

Series: AD-0601

Location: Silver Spring, MD

Salary: Starting at $72,750, (Band A), $87,198 (Band B), $103,690 (Band C) *Starting salary is minimum of band and may be set higher, commensurate with experience.

Work Schedule: Full Time

Cures Band(s): Bands A, B, and C

Travel Requirements: 25% or less

Full Performance Band Level: Band C

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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 the Agency) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

The mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter (OTC) and prescription drugs, including biological therapeutics and generic drugs. CDER is seeking individuals/leaders with a commitment to scientific excellence and innovative

thinking to lead a dynamic and diverse organization.

The Patient Focused Drug Development (PFDD) program is leading pathbreaking work, developing sustainable approaches to include the patient's voice in drug development, coordinating development of new regulatory guidance, pursuing international harmonization of related standards, engaging directly with patients and caregivers, and overseeing development of sound measurement tools to capture the patients' experience.

Duties/Responsibilities (Band A)

- Provides assistance related to the planning, development, administration, execution, and coordination of programs, initiatives, and policies in PFDD. Participates in the development and implementation of programs (e.g. communication and process improvement initiatives); assists in the development of preliminary operating criteria and procedures, policy issuances, standards, and protocols to be followed throughout PFDD
- Assists in the development of policy recommendations and consistency with program implementation of regulations, Center policies, and precedents on patient-focused regulatory and health science programs.
- Supports the planning, design, implementation, and analysis of regulatory science programs, including rulemaking and guidance development for the PFDD program.
- Conducts research on studies of continuing projects concerned with the Center's primary regulatory science programs. Reviews methodology of past and proposed regulatory program options for achieving Agency public health goals and assists subject- matter experts in the design of regulatory science programs conducted within the Center.
- Uses CDER's external resources or information related to Patients' Experience pilot webpage to conduct outreach and engages with external stakeholders to advance the integration of patient input into drug development and decision making.
- Performs other duties as assigned.

Duties/Responsibilities (Band B)

- Provides recommendations on the planning, design, implementation, and analysis of regulatory science programs, including rulemaking and guidance development.
- Conducts studies on continuing projects concerned with the Center's primary regulatory science programs. Evaluates methodology of past and proposed regulatory program options for achieving Agency public health goals and assists subject- matter experts in the design of regulatory science programs conducted within the Center.
- With moderate oversight, leads the planning, development, administration, execution, and coordination of programs, initiatives, and policies in PFDD. Participates in the development and implementation of programs (e.g. communication and process improvement initiatives); assists in the development of preliminary operating criteria and procedures, policy issuances, standards, and protocols to be followed throughout PFDD.
- Applies new methods for resolving regulatory science problems. Extends and modifies approaches, precedents and methods to solve a variety of regulatory problems. Study findings are considered for incorporation into Agency guidelines and regulations and affect industry practices nationwide.

- Participates regularly in consultations with medical reviewers and other policy staff concerning ongoing and established scientific studies or other projects; collates and synthesizes scientific information from subject matter experts in support of the development of policies and regulations related to the science of patient input.
- Performs other duties as assigned.

Duties/Responsibilities (Band C)

- Oversees the conduct and implementation of research projects, grants, and contracts designed to move the science of patient input forward at both the FDA and in drug development as a whole.
- Conducts studies on continuing projects concerned with the Center's primary regulatory science programs and evaluates methodology of past and proposed regulatory program options for achieving Agency public health goals and assists subject- matter experts in the design of regulatory science programs conducted within the Center.
- Reviews and analyzes project implementation plans for improvements and prepares and provides timely status reports to the supervisor and management. Makes recommendations and implements corrective actions.
- Leads the planning, development, administration, execution, and coordination of programs, initiatives, and policies in PFDD. Participates in the development and implementation of programs (e.g. communication and process improvement initiatives); assists in the development of preliminary operating criteria and procedures, policy issuances, standards, and protocols to be followed throughout PFDD.
- Applies new methods for resolving regulatory science problems. Extends and modifies approaches, precedents and methods to solve a variety of regulatory problems. Study findings are considered for incorporation into Agency guidelines and regulations and affect industry practices nationwide. Drafts documents to present findings and recommendations as required.
- Provides professional regulatory science policy consultative services to other Office of Center Director and FDA components, and other government agencies as needed. Works to achieve consistent policy approaches.
- Serves as a mentor to staff, trainees and other fellows.
- Performs other duties as assigned.

Supervisory Responsibilities: N/A

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.

- One year probationary period may be required.
- 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: AD-0601

Candidates must meet education requirements of a bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Professional Experience (Band A):

- Excellent proactive project management and problem-solving skills.
- Skill in effective/efficient meeting management.
- Strong analytical and communications skills, both oral and written.
- Knowledge of computer applications, including expertise using Microsoft Office Suite and the ability to use computer databases to conduct literature searches.
- Excellent interpersonal, analytical, organizational and time management skills.

Professional Experience (Band B):
Experience listed in Band A above and:

- Possession of at least two years of experience in a regulatory or clinical research environment, this may include experience gained during doctoral work.
- Excellent interpersonal, analytical, organizational and time management skills.

Professional Experience (Band C):
Experience listed in Bands A and B above and:

- Mastery in identifying problems, gathering and analyzing information, drawing conclusions, recommending solutions, preparing reports and options and developing presentations is required.
- Ability to distill large amounts of information into specific takeaways.

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: Position Sensitivity-Non-Sensitive- Moderate Risk. If not previously completed, 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 these 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

Submit resume or curriculum vitae with cover letter by **(January 14th, 2022)** to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions please contact Ashley Corum-Lawson, Supervisory Administrative Officer, Ashley.Corumlawson@fda.hhs.gov. Please reference Job Code: T-21-605-ABC

Announcement Contact

For questions regarding this Cures position, please contact Ashley.Corumlawson@fda.hhs.gov.

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