Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Executive Programs (OEP)
Division of Advisory Committee and Consultant Management (DACCM)

Application Period: November 20, 2023 – December 11, 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: Health Science Administrator

Series: AD-0601

Location(s): Silver Spring, MD

Salary:
$94,199-$127,096 (Band B)
$112,015-$155,978 (Band C)

Work Schedule: Full Time

Cures Band(s): Band B

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

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) 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 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 looking for leaders with a

commitment to scientific excellence and innovative thinking to lead a dynamic and diverse organization.

The Office of Executive Programs (OEP) oversees a variety of Center-wide programs, including executive project management, the Center's executive secretariat function, scientific advisory committees, training and development, CDER's ombudsman, and program and administrative management.

The Division of Advisory Committee and Consultant Management (DACCM) is responsible for directing and managing CDER programs involving the use of special government employees (SGE) working for CDER either as scientific consultants or advisory committee members. The division supports DACCM's role by ensuring the work and information surrounding advisory committees is complete and accurate, and the utilization of external experts is well planned and executed in a timely manner.

Duties/Responsibilities

As a **Health Science Administrator**, the incumbent serves as a Designated Federal Officer (DFO) for the advisory committees responsible for implementing the administrative aspects of hosting, commencing and closing an Advisory Committee Meetings under the Federal Advisory Committee Act (FACA) requirements. Responsibilities include identification, appointment and onboarding of Experts and Consultants, advisory committee meeting logistics and public participation. The incumbent also runs and reports on the committee management activities to include financial operations, charter renewals and annual review requirements for assigned meetings.

Works with the Office of New Drugs (OND) to fully understand the scientific basis for the advice and recommendation that the Agency seeks from its advisory committees.

Band B:
Performs research using a variety of sources such as U.S. treatment guidelines, Pubmed, Up-to Date, ClinicalTrials.gov on current clinical practice guidelines and product use related to specific advisory committee meeting topics. Collaborates and fully participates in discussions with other Agency professionals in the development of the competing and affected products list (C/AP List) for advisory committee meetings and agency-directed assignments. Informs participants (Chair) of the findings to ensure meeting participants and decision makers are notified of approved products, off-label products and pending Investigational New Drug (IND) Applications/New Drug Applications (NDAs) for the proposed indication that could potentially be impacted by the outcome of an Advisory Committee (AC) meeting.

Participates in developing and implementing programs, plans, and communications to identify and review and resolve issues that have a major impact on the Division and numerous offices across the Center. Analyzes issues and applies varied and multiple statutes, regulations and policies in determining effective resolution of issues related to advisory committee meetings.

Manages very strict timelines surrounding committee meeting logistics, public notice requirements, and meeting materials, ensuring many dependent activities are complete.

Develops communication plans to select the best-qualified committee members for subcommittees and other special assignments. Uses the CDER Advisory Committee Members and Consultants database to identify and maintain knowledge of the comparative competencies of practitioners and scientists working in the field of interest in order to recommend outstanding candidates from the diverse scientific disciplines needed to maintain a balance of skills and the highest level of competence in the committee membership.

Approves or calls meetings of the advisory committees; serves as an active participant in the Advisory Committee meetings to discuss committee actions; evaluates and makes decisions to adjourn the meetings when it is in the public interest; develops or approves meeting agendas; may serve as chair in the absence of the appointed chairperson; determines when meetings should be closed in conformity with legal requirements; maintains all committee records.

Administers the on-going review of scientific issues assigned to the various advisory committees. Provides a wide variety of information to the consultants (committee members) as a background for reviewing and evaluating issues. Collects and provides information considered to be essential for members to have in order to adequately evaluate the assignment. Assists in producing summary statements of committee findings and recommendations for use by the senior officials of the Agency based on committee evaluation.

Band C:
Meet duties and responsibilities outlined in Band B above.

Independently performs in-depth research using a variety of sources such as U.S. treatment guidelines, Pubmed, Up-to Date, ClinicalTrials.gov on current clinical practice guidelines and product use related to specific advisory committee meeting topics. Collaborates and leads discussions with other Agency professionals regarding products and entities that could potentially be impacted by the outcome of an assignment or Advisory Committee (AC) meeting.

Analyzes issues and applies Federal statutes, regulations, and policies to recommend effective resolution of issues related to advisory committee meetings. Independently develops and implements suggested solutions to resolve issues that have a major impact on the public health and programs administered by DACCM and other Center program offices associated with the planning and implementation of advisory committee meetings. The incumbent may be required to address program time and resource constraints, processing delays and issues relating to meeting logistics.

Independently manages and prioritizes very strict timelines surrounding committee meeting logistics, public notice requirements, and meeting material, ensuring many dependent activities are complete.

Leads the development and implementation of programs, plans, and communications to select the best-qualified committee members for subcommittees and other special assignments. Uses the CDER Advisory Committee Members and Consultants database to identify and maintain knowledge of the comparative competencies of practitioners and scientists working in the field of interest in order to recommend outstanding candidates from the diverse scientific disciplines needed to maintain a balance of skills and the highest level of competence in the committee membership.

Approves or calls meetings of the advisory committees; serves as an active participant in the Advisory Committee meetings to discuss committee actions; evaluates and makes decisions to adjourn the meetings when it is in the public interest; develops or approves meeting agendas; may serve as chair in the absence of the appointed chairperson; determines when meetings should be closed in conformity with legal requirements; maintains all committee records. Follows established principles to arrange meetings that are reasonably accessible and at convenient locations and times; publishes adequate advance notice of meetings in the Federal Register; opens advisory committee meetings to the public (with some exceptions); makes available for public inspection, subject to the Freedom of Information Act, papers and records, including detailed minutes of each meeting; and maintain records of expenditures.

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 *supervisory* 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 legalaction. 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.

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:
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.

Desired Professional Experience:
Our ideal candidate will possess:

- Knowledge of the FDA advisory committee process. Project Management skills to meet complex and high priority deadlines with multiple concurrent deliverables.
- Interpersonal skills and proven communication ability to develop strategic contacts and outreach to various audiences, including executive leadership, external members of the healthcare community, members of professional organizations, and patient safety groups.
- Ability to identify problems, gather information, draw conclusions, recommend solutions, prepare papers and reports for publication, provide advice to other regulatory scientists, and negotiate acceptance and implementation of recommendations.
- Ability to understand the theories, principles and methods in regulatory science and possibly any associated scientific disciplines sufficient to allow the employee to review a variety of complex industry applications, to apply new scientific and technological developments to novel and critical problems which cannot be solved by the use of conventional methods; and to extend and modify approaches, precedents and methods in order to resolve and prevent obscure and unprecedented problems.
- Knowledge of the Federal Food, Drug, and Cosmetic (FD&C) Act.
- Knowledge of FACA, the FDA drug review and regulatory process.

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

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 **December 11, 2023,** 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”.

Please reference Job Reference ID: T-20-129-Band B or Band C in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Crystal Coulter, Management Analyst, Crystal.Coulter@fda.hhs.gov

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

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