Title 21 Cures Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation & Research (CDER)
Office of New Drugs (OND)
Multiple VacanciesOffice of Rare Diseases, Pediatrics, Urologic & Reproductive Medicine (ORPURM)
Division of Rare Diseases and Medical Genetics (DRDMG)

Application Period: Tuesday, December 07 – Thursday, January 6, 2022

Area of Consideration: U.S. Citizens

Position: Science Policy Analyst

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Band C Starting at $103,690

Work Schedule: Full Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

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

This vacancy is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act.

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 are safe, and effective.

The FDA's Center for Drug Evaluation and Research (CDER) is looking for leaders with a commitment to scientific excellence and innovative thinking to lead a dynamic and diverse organization. The Office of New Drugs (OND), Office of Rare Diseases, Pediatrics, Urologic & Reproductive Medicine (ORPURM), Division of Rare diseases and Medicval Genetics (DRDMG) is conducting a search for talented leaders for the position of **Science Policy Analyst**.

OND is a dynamic, purpose-driven organization dedicated to the review of new drug applications (NDAs), interactions with the pharmaceutical industry and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multi-disciplinary organization engaged in the oversight of human drug trials in the United States, in review of NDAs and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over-the-counter (OTC) drug products.

The Rare Diseases Team (RDT) in the Division of Rare Diseases and Medical Genetics (DRDMG), Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM), Office of New Drugs (OND) is offering multiple hiring opportunities for Science Policy Analyst positions.

The RDT's mission is to facilitate, support, and accelerate the development of drugs and therapeutic biologics for rare diseases by coordinating the development of CDER policy, procedures, educational training, and stakeholder engagement for the review of treatments for rare diseases. The RDT is looking for multiple Science Policy Analysts with primary expertise in one or more of the following:

- Conduct and mentoring of regulatory science research for rare diseases
- Contribute, coordinate, and support for regulatory research, grant writing and administration, and publications
- Data science and informatics
- Stakeholder engagement and education (patient and academic research communities)

The incumbent serves on the RDT as a Science Policy Analyst for their area of expertise to develop, maintain, and manage the administration the RDT's multiple obligations to facilitate internal agency coordination and external engagement for our multiple external stakeholders (e.g. industry, foundations, and patient advocacy groups).

Duties/Responsibilities

The Rare Diseases Team (RDT) in the Division of Rare Diseases and Medical Genetics oversees the full range of drug development for biologics and drug products for rare diseases by coordinating the development of CDER policy, procedures, training, and stakeholder outreach for the review of treatments for rare diseases in OND's new rare disease hub. The incumbent serves serves as a Science Policy Analyst on the Rare Diseases Team Staff in the Division of Rare Diseases and Medical Genetics, providing support to the Supervisory Associate Director on matters that have a direct effect on the review and evaluation of rare disease drug development actions, policies, and programs. In this role, the incumbent assists with the conduct and implementation of guidances, workshops, research projects, grants, and stakeholder engagement both internal and external designed to facilitate, support, and accelerate the development of drugs and therapeutic biologics for rare diseases at both the FDA and in rare disease drug development as a whole. Duties include:

Serves as a public-health focused subject matter expert with supervision to support the Supervisory Associate Director for Rare Diseases on strategic programs and policies, serves as a key liaison to Agency-level staff, other Federal and international agencies, industry and academia on rare disease issues, represents the Center on internal and external committees, and working groups, and presents Center policies and procedures in public forums. Participates intra- and inter-agency interactions to develop and implement strategy and policies that require coordination and negotiations among stakeholders.

Builds strategic relationships with potential stakeholders, champions of change, leaders, and their teams in order to garner buy-in and achieve project objectives with supervisory oversight such as National Organization for Rare Disorders, National Institutes for Health, or industry organizations.

Maintains a continuing awareness of the health, scientific, and legislative activities and problems of various international organizations in fields of importance to FDA's mission and promotes international rare disease scientific programs. Recommends agency actions in response to significant developments and establishes effective mechanisms for action. Presents recommendations to top level agency management that may include senior divisional, office, center leadership

Builds program knowledge and related resources related to the regulatory review processes and interactions particularly relevant in regulatory decision-making for the development of drug products for rare diseases.

Implements and maintains tracking related to rare disease PDUFA goals or mandates, benchmarks or other metrics to assess whether the desired outcomes were attained. Contributes to the development of new systems to achieve PDUFA goals or mandates.

Uses understanding of project objectives and progress to engage in and select the appropriate outreach and engagement mechanisms (i.e.,small groups, one-on-one meetings, virtual communication, etc.). Assists the team with effective utilization of proper outreach and engagement mechanisms.

Participates in the designing, developing, and implementing programs to facilitate the education of stakeholders on rare disease drug development.

Supports the management of processes to advise regarding rare disease policy and guidance development for review through OND senior leadership.

Promotes excellence in rare disease scientific research and grant management as a sound basis for the development of treatments for rare diseases and tracks research projects for knowledge management that relate to the review and regulation of drugs and therapeutic biologics for rare diseases.

Assists OND's Rare Diseases Team with facilitation of cross center working groups as well as implementation and management initiatives pertaining to rare disease drug development. Able to record key assessments and information to relay to the Associate Director.

Facilitates and consults with CDER review and policy staff throughout implementation of the PDUFA VI and 21st Century Cures requirements for rare disease drug development, such as planning for workshops, development of guidance documents, development of case study examples, etc.

Assists in the development, coordination, and implementation of program improvements and new procedures designed to enhance program performance on rare disease drug development activities broadly throughout CDER and across FDA.

Follows the Center's Records Management Policy, ensuring proper documentation and storage of all work.

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 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:

General Medical and Healthcare Series, 0601

The individual occupational requirements for the 0601 Analyst series can be found at: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/0600/general-health-science-series-0601/

Basic Qualifications:

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 US Department of Education at the time the degree was obtained.

Professional Experience:

Excellent collaborative skills, capable of working with a wide range of individuals of all levels from both public and private organizations, including the Center, Office of the Commissioner, other FDA Centers, other Federal agencies, and Congress, as well as the scientific/medical community, academia, and industry, which requires tact, diplomacy and technical expertise in communicating Center/Agency policies.

Excellent verbal and written communication skills in order to develop policy, guidance(s) to industry, internal procedures, Center-level responses to congressional inquiries, etc.

Excellent skills in critical thinking and strategic vision, to advance OND's rare disease policies, research agenda, training, and collaboration across other divisions, offices and stakeholders.

Solid understanding of the regulations and polices as well as experimental design, theories and practices utilized in new drug evaluation.

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: This position requires a Public Trust security clearance and the incumbent has access to sensitive, proprietary, or financial information.

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 a resume with cover letter expressing your desired division(s) of interest to: ond-employement@fda.hhs.gov. Candidate resumes may be shared with hiring officials within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". **Please reference source code: OND-DRDMG-1003 in the subject line of your submission.**

Announcement Contact

For questions regarding this Cures position, please contact ond-employment@fda.hhs.gov.

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

FDA is an equal opportunity employer.