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 New Drugs (OND)
Clinical Data Staff (CDS)

Application Period: October 12, 2023 - October 26, 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: Clinical Analyst

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $112,015 - $155,978

Work Schedule: Full-Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: You WILL NOT 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 and prescription drugs, including biological therapeutics and generic drugs.

The Office of New Drugs (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 Clinical Data Staff (CDS) provides clear, accurate, and comprehensive safety data quality assessments and safety data analyses in collaboration with clinical reviewers.

Duties/Responsibilities

As a **Clinical Analyst**, the incumbent provides clear, accurate, and comprehensive safety data quality assessments/analyses and advising on the full span of scientific/policy issues related to the development and approval of new drug products and biologic drug products in coordination with other CDER offices, including Office of Translational Sciences, Office of Pharmaceutical Quality, and Office of Compliance. The incumbent serves on a multidisciplinary team of health care professionals.

- Reviews and evaluates clinical study protocols and reports submitted in New Drug Applications (NDAs)/Biologic License Applications (BLAs), supplemental NDAs/BLAs, new Investigational New Drugs (INDs), new protocols and protocol amendments, and Emergency INDs.
- Reviews background packages and sample safety datasets to assess appropriateness of controlled terminology and safety dataset structure and reviews safety data pooling strategy in Statistical Analysis Plan (SAP) to assess appropriateness.
- Develops Safety Data Analysis Plan (SDAP) with the clinical review team and executes the SDAP in the review process. Assesses sufficiency, integrity, and quality of safety datasets and provides a written report regarding assessment of safety data sufficiency, integrity, and quality to the clinical review team within OND.
- Audits 10% of case report forms (CRFs) according to the number of subjects in the safety population, conducts preliminary safety assessment, and provides a written report to the clinical review team within OND.
- Performs comprehensive safety data analyses and provides a written report containing safety tables and figures to clinical review team while also creating additional safety tables and figures based on the requests of clinical review team. Conducts exploratory and in-depth safety data analyses for specific safety

signals and issues.

- Performs safety data verification in Clinical Study Report (CSR), Integrated Summary of Safety (ISS), and draft label; provides a written report regarding identified discrepancies to clinical review team. Reviews submissions in support of revisions to labeling of approved NDAs/BLAs. This often includes new data from clinical trials.
- Pulls safety data from multiple clinical trials with an appropriate pooling strategy to avoid capturing incorrect safety signal detection and omitting potential safety signals. Performs safety data analyses by adjusting treatment exposure; suggests systemic safety analyses and methods for specific safety signals; and participates in work related to FDA guidance and policies.
- Convenes meetings with Offices throughout the Office of New Drugs (OND), as needed, to plan, evaluate interim progress, and discuss with clinical review team to align on expectations and deliverables.
- Presents safety data quality assessment and analyses in review and sponsor meetings with the Office of New Drugs (OND).

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.

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, AD-0601 Series

For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Education:

Our ideal candidate will possess an advanced degree in life or biomedical sciences, pharmacology, chemistry, biology, or a related field (including PharmD, Ph.D., M.D., D.O., or nursing degree such as nurse practitioner).

Professional Experience:
Our ideal candidate will possess:

- Proficient data analytical/programming skills in programming software such as R, Python, and SAS.
- Strong organizational, analytical, and interpersonal skills.
- Demonstrated research experience in chemistry, biology, pharmacology, toxicology, or a related field of biomedical science.
- Significant experience in identifying, articulating, addressing, and resolving unique, far-reaching and/or previously unresolved and precedent-setting problems and complex issues.
- Professional knowledge of, and skill in applying theories, concepts, principles, and practices of medicine sufficient to serve as a recognized technical authority and consultant in a specialized technology and broad program that affects national and international interests, including the well-being of the American public.
- Mastery professional knowledge and understanding of current FDA, CDER, and OND regulations, policies, and procedures pertaining to safe and effective drugs and biologics.
- Strong interpersonal and, expert written and verbal communications skills to provide

advice and guidance to senior management and employees and prepare a variety of written reports and documents.
- Expertise in analytical, fact-finding, and investigative techniques and skills to carry out the Division's mission.

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

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

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 with cover letter and unofficial transcripts by **October 26, 2023,** to Keya Whitaker at ONDIORecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within the 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: IO-23-046** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Danielle Wright at Danielle.wright@fda.hhs.gov.

smoke free environment.

FDA is an equal opportunity employer.