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 Regulatory Policy (ORP)

Application Period: October 1, 2024 – October 31, 2024

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: Scientific Redactor

Series: AD-0696

Location(s): Remote Anywhere in the U.S.

Salary:
$99,200 - $133,845 (Band B)

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 and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Regulatory Policy (ORP) is to provide Center oversight and leadership in the development of regulations, policies, procedures, and guidance's that affect the drug approval process, and in the development of new legislation. Also, ORP manages the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and Food and Drug Administration's public disclosure regulations.

The mission of the Division of Disclosure Policy (DIDP) is to provide Center oversight and leadership in the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and FDA's public disclosure regulations.

Duties/Responsibilities

As a **Scientific Redactor,** the incumbent will apply redaction skills and good judgment in appropriately redacting scientifically rich information and documents by identifying and removing confidential information before public disclosure. Informed or awareness of scientific terminology and concepts and may be required to consult with FDA's program areas on important and sensitive issues and inform the supervisor of sensitive and/or challenging requests.

Band B:

- Ensures that all responses are accurate and contain only information which is disclosable as provided under the Freedom of Information Act (FOIA) and FDA policy. FOIA requests and other disclosure projects are assessed, evaluated, and completed in a timely manner. Reviews and organizes materials, documents, and records for disclosure to ensure that they are accurate, clear, and concise.
- Evaluates information to ensure that it is complete and accurate and follows up to make sure that agreements and commitments are fulfilled in a timely manner. Plan and organize requests for information and manage multiple tasks simultaneously. Sets clear priorities, goals and expectations, tracks progress against goals, ensures feedback and addresses problems and issues promptly by maintaining a good working relationship with supervisor and team leader.
- Utilizes processes and methods of collecting and synthesizing information from various sources in an objective, unbiased manner; understands, interprets, and makes sound decisions relative to information disclosure.
- Analyzes information needs, determines an information plan, and, by careful evaluation, ensures that information is within the guidelines provided for under the Freedom of Information Act, Trade Secrets Act, Federal Food, Drug and Cosmetic (FD&C) Act and related statutes and regulations implemented by FDA.
- Maintains an awareness of current developments in CDER and uses this knowledge in the process of assembling appropriate information for disclosure. Seeks information to

understand problems, needs and expectations and methodically and systematically establishes reliable data to support disclosure decisions.

- Applies knowledge to appropriately identify issues, problems, or opportunities, and determines if action is needed. Applies investigative techniques to acquire new data. Applies useful, accurate and comprehensive models and methods. Works cooperatively with others to share information and to build and maintain mutually beneficial partnerships to accomplish objectives and achieve results.
- Provides support to agency representatives from the Office of Chief Counsel in the collection and/or preparation of background information and testimony of FDA officials in court cases on defending FDA's position on the disclosure of requested information. Prepares recommendation for document request denials for information exempt from disclosure.
- Recommendations must include technical justifications and appropriate evidentiary support. Consults with appropriate FDA components to assure that information requests are complete and satisfied in a timely manner. Works as collaborative team member in discussing and addressing issues related to information disclosures.

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 is required.
- Financial Disclosure is required.
- Ethics Clearance is required.
- Background Investigation/Security Clearance is required.

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:

Consumer Safety, AD-0696 Series:

A. A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

OR

B. Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

Experience Requirement:

Work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the band level of the position. Qualifying experience involves enforcing laws and regulations to protect consumers from foods, drugs, cosmetics, fabrics, toys, equipment, and household products that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.

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

Desired Skills, Experience, or Education:
Our ideal candidate will possess:

- Candidates with 2+ years of experience in a relevant scientific field, consumer/drug law, scientific redaction or editing, or privilege review and eDiscovery are preferred.
- Knowledge of the Freedom of Information Act (FOI), Privacy Act, or Federal Food, Drug and Cosmetic (FD&C) Act or similar statutes is required.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/Moderate 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 actions.

Ethics Clearance Requirements

This position requires 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 **October 31, 2024**, to: CDER-ORP-Cures-Hiring@fda.hhs.gov. On the subject line, please reference "**Scientific Redactor Band B"**. 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".

How I Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact CDER-ORP-Cures-Hiring@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.