



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 Translational Sciences (OTS)

Application Period: October 17, 2022 – October 28, 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: Associate Director for Quality Management **Series:** AD-0401, 0405, 1320

Location(s): Silver Spring, MD

Salary: Starting at \$148,484

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: Up to 25%

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 streamlined 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 are 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.

Duties/Responsibilities

As an **Associate Director for Quality Management (ADQM)**, the incumbent will serve as an advisor for the Director and Deputy Director of the Office of Study Integrity and Surveillance (OSIS), providing expert level advice on matters pertaining to stakeholder interactions encompassing the strategic development and enhancement of external relationships with the scientific, academic, and industry communities, arising from on-going and new CDER goals, policies and initiatives within the Office of Study Integrity and Surveillance.

Provides guidance on incorporating OSIS's programs and policies for the bioavailability/bioequivalence (BA/BE) and Good Laboratory Practices (GLP) inspection programs to support Food and Drug Administration (FDA's) human drug product application decision making.

Develops curricula for inspections and reviewer development regarding GLP, pharmacology, pharmacokinetics, pharmacodynamics, bioanalysis, and principles of associated scientific disciplines to formulate solutions to unyielding or controversial inspections problems.

Maximizes the capabilities of OSIS staff and contributes significantly developmental curriculum to raise their level of competency and enhance interactions with the scientific community. This includes developing specific expectations and standards for inspection oversight for OSIS's BA/BE and GLP programs.

Provides authoritative expert advice and in areas of multi-disciplinary scientific advancements, inspectional outreach, internal and external stakeholder interactions, and development and enhancement of external relationships with the scientific, academic, and industry communities, arising from new CDER initiatives.

Develops and implements regulatory science policy for top management review within and outside of OSIS, scientific initiatives, and communication about those policies and initiatives.

Represents the Office/Center based on subject matter expertise and communicates overall project goals and provides technical direction, oversight, and facilitation of projects. Assists in the preparation of summary reporting documents and briefings to senior OSIS, CDER and FDA leadership, as needed.

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:

Pharmacologist Series [0405 Basic Requirements](#)

Biologist Series [0401 Basic Requirements](#)

[Chemistry Series 1320 Basic Requirements](#)

Desired Education:

Doctoral or masters level degree in scientific field.

Desired Professional Experience:

- Experience in applying knowledge of a major therapeutic area and/or related areas to assess, analyze or evaluate study designs, data, or conclusions, submitted by sponsors

of pharmacology or biopharmaceutics submissions associated with IND, NDAs, BLAs, and ANDAs to support marketing of a drug.

- Ability to communicate in writing in order to develop policy, guidance(s) to industry, internal procedures, Center-level responses to congressional inquiries, etc.
- Demonstrated work experience leading and advising senior staff at all levels of 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.
- Demonstrated experience developing tools for scientific advancement and didactic programming.
- Demonstrated experience creating resources, including internet-based resources, to increase efficiency, consistency, and sophistication of science-based programs.
- Demonstrated experience communicating strategic initiatives to academic and non-scientific audiences.
- Demonstrated experience creating collaboration opportunities for multi-disciplinary initiatives.

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/Low Risk investigation, and the incumbent has access to documents and facilities.

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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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

Applicants should submit a letter of interest (cover letter) and current resume by **October 28, 2022**, to CDEROTSHires@fda.hhs.gov. Please adhere to the following submission protocol:

- **Cover letter and resume should be one combined PDF document with the following naming convention: Last Name, First Name**
- **Reference 'Associate Director for Quality Management' in the subject line of the email.**

Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume or email with "do not share".

How I Will Be Evaluated

Candidates may be evaluated based on an interview, experience describe in resume, 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 CDEROTSHires@fda.hhs.gov

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

FDA is an equal opportunity employer.

