



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 Generic Drugs (OGD)
Multiple vacancies

Application Period: September 8, 2022 – October 7, 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: Regulatory Health Project Manager

Series: AD-0601, 0660, 0696

Location(s): Silver Spring, Maryland

Salary: Starting at:

\$89,834 (Band B)

\$106,823 (Band C)

Work Schedule: Full Time

Cures Band(s): Band B/C

Full Performance Band Level: Band C

Travel Requirements: Less than 25%

Bargaining Unit: 3591

Relocation Expenses Reimbursement: Relocation expenses will not be paid.

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 Generic Drugs (OGD) oversees the development and implementation of standards for the safety and effectiveness of generic drugs. OGD reviews and evaluates Abbreviated New Drug Applications (ANDAs) and their amendments or supplements and determines approvability. OGD establishes bioequivalence specifications for drug products and develops guidelines for bioequivalence reviews, industry protocol and studies. OGD oversees all aspects of labeling submissions for ANDAs.

The Office of Bioequivalence (OB) ensures that submitted bioequivalence data meets rigorous scientific and regulatory standards to support approval of high quality, affordable generic drugs.

The Office of Regulatory Operations (ORO) reviews Abbreviated New Drug Applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generics drugs including complex products for regulatory filing and labeling acceptability and the overall management of generic drug applications.

The Office of Safety and Clinical Evaluation (OSCE) supports the timely assessment of ANDAs submitted under section 505(j) of the Federal Food, Drug, and Cosmetic (FD&C) Act on equivalence standards for generics drugs with attention to coordinating complex scientific considerations. OSCE also supports the development and implementation of safety programs, specific to a risk evaluation and mitigation strategy, during the generic drug application review.

Duties/Responsibilities

As a **Regulatory Health Project Manager**, the incumbent provides technical direction to team members within OGD to support the public health mission to help ensure high quality, affordable generic drugs are available to the American public.

Band B:

- Participates in regulatory science research to establish equivalence standards for generic drugs that will ensure therapeutic equivalence. Provides pre-submission scientific advice to ANDA sponsors on equivalence standards for generics drugs.
- Serves as a scientific, regulatory, and technical resource providing assessment and evaluation for the submission requirements of generic drug applications, generic drug process and program activities within OGD.
- Recommends input and innovative strategies when collaborating within the Office to modify and develop systems, policies, and procedures.
- Supports the development of various deliverables such as regulations, guidance, Manuals of Policy and Procedures, and other statements including a policy component.

Band C:

- Meets duties and responsibilities outlined in Band B above.
- Publishes and maintains public facing databases as it relates to the requirements described in section 505(j) of the FD&C.
- Replies to correspondence from regulated industry and other interested parties and provides counsel as needed in order to inform and educate on policies, application procedures, and other guidance related to the generic drug program.

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 Series, AD-0601:

Degree: A 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.

For more information, please see: [OPM Occupational Series Qualification Requirements, 0601](#)

Pharmacy Series, AD-0660:

Degree: A doctoral degree in Pharmacy.

For more information, please see: [OPM Occupational Series Qualification Requirements, 0660](#)

Consumer Safety Series, AD-0696:

Degree: A bachelor’s or graduate/higher level degree in quality assurance or a related degree.

For more information, please see: [OPM Occupational Series Qualification Requirements, 0696](#)

Desired Professional Experience:

Our ideal candidate will possess:

- Ability to manage a challenging project with several parallel processes from start to finish, with recognition of milestones and challenges to completion.
- Demonstrated experience with applying project management techniques and concepts to manage large, complex projects with diverse stakeholders.
- Ability to independently identify and analyze problems
- Experience assessing information/data and making decisions on issues related to complex drug products.
- Experience communicating with staff at all levels of the organization and varying levels of domain expertise in a timely manner.
- Experience utilizing organizational and time management skills.
- Experience collaborating with or negotiating consensus among a team or workgroup.

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/Moderate-risk (Band B); Non-sensitive/High-Risk (Band C)

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.

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

How to Apply: Submit resume or curriculum vitae with cover letter by **October 7, 2022**, to: OGDHiring@fda.hhs.gov. Candidate resumes may be shared with hiring official within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions, please contact OGDHiring@fda.hhs.gov.

Announcement Contact

For questions regarding this Cures position, please contact OGDHiring@fda.hhs.gov.

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

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