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)
Immediate Office (IO)

<table>
<thead>
<tr>
<th>Application Period:</th>
<th>July 7, 2022 - July 20, 2022</th>
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<tbody>
<tr>
<td>Area of Consideration:</td>
<td>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.</td>
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<td>Position:</td>
<td>Deputy Super Office Director for Operations</td>
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<td>Series:</td>
<td>AD-0601</td>
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<tr>
<td>Location(s):</td>
<td>Silver Spring, MD</td>
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<tr>
<td>Salary:</td>
<td>Starting at $168,914</td>
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<td>Work Schedule:</td>
<td>Full Time</td>
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<td>Cures Band(s):</td>
<td>Band F</td>
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<td>Full Performance Band Level:</td>
<td>Band F</td>
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<tr>
<td>Travel Requirements:</td>
<td>25 % or less</td>
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<td>Bargaining Unit:</td>
<td>8888</td>
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<td>Relocation Expenses Reimbursement:</td>
<td>You may qualify for reimbursement of relocation expenses in accordance with agency policy.</td>
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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 Generic Drugs (OGD) is to provides oversight, leadership, strategic direction, and, and ensure high-quality, affordable generic drugs are available to the American public. Oversees the development and implementation of standards for the safety and effectiveness of generic drugs, the review and assessment activities of Abbreviated New Drug Applications (ANDAs), their amendments and supplements to determine their approvability according to standards consistent with the Food, Drug and Cosmetic (FD&C) Act and relevant sections of the regulations.

**Duties/Responsibilities**

As the **Deputy Super Office Director for Operations**, the incumbent participates fully with the Office of Generic Drugs (OGD) Director in providing executive leadership and direction to OGD. Responsible for providing oversight for the support of all OGD operational elements including formulating and establishing Office goals in assessment and approval of human generic drug products and executing those goals by providing the regulatory and operational strategy, establishing the efficient processes, and allocating resources.

- Provides direction and leadership on projects which advance the state-of-the-art oversight of scientific and regulatory informatics, ensuring best practices and approaches are utilized in the development, delivery, enterprise resource planning, and business intelligence of all data management initiatives within OGD.
- Responsible for evaluating the effectiveness of complex regulatory programs in meeting established goals and objectives across CDER and FDA Offices and with a broad range of organizational sub-units developing and executing a plan for improvement based on evaluation results.
- Assists with implementing the Executive Performance Reporting and implementation including overseeing the analysis of workload and program performance across OGD. In addition, the incumbent has oversight as a major orchestrator of the development and implementation of programs, processes, and strategic initiatives to support important Office, Center, and Agency priorities.
- Provides oversight of activities related to the implementation and meeting of GDUFA commitments and oversight of review management activities to ensure adoption of best practices and official policies such as the 21st Century Review Process and the Good Review Management Principles guidances with the goal of achieving a highly efficient and effective review process.

**Supervisory Responsibilities:** Manages one or more portfolios and provides leadership and direction for multiple, smaller program offices in coordination with the Super Office Director. Provides occupational-specific technical and administrative direction 25 percent or more of the time to three or more subordinate employees performing the work and functions of the organization.
Oversee efforts for ensuring robust, efficient, and effective regulatory operations, providing leadership and expert advice on processes and procedures, organization structures, and change management within OGD. Receives general supervision from the OGD Director. Manages staff operations consulting with the OGD Director on policy-setting or extremely controversial situations. Exercises sound judgement and provides expert technical advice and assistance.

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/Safety 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, 0601*

Degree: 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 [U.S. Department of Education](https://www.ed.gov) at the time the degree was obtained.

Meets the Office of Personnel Management (OPM) [OPM Occupational Series Qualification Requirements](https://www.opm.gov/qualifications/)

**Professional Experience:**

Our ideal candidate will possess:

- Executive leadership experience with an established track record in leading organizations of significant size and complexity.
- Knowledge of Generic Drug development and knowledge of regulatory standards for safety and effectiveness of human drugs.
- Effective communicator who can drive collaboration, empower staff, and is committed to the Public Health 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](https://www.ed.gov).

**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.

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 July 20, 2022 to: Lauren.Sams@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact
For questions regarding this Cures position, please contact Lauren.Sams@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.