



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 Pharmaceutical Quality (OPQ)
Office of Office of Testing and Research (OTR)

Application Period: October 15, 2021 – October 21, 2021

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.

Commissioned Corp Officers may apply.

Position: Deputy Office Director

Series: AD – 1320/893/401

Location(s): Silver Spring, MD or St. Louis, MO

Salary: Starting at \$ 163,962

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 25% or less

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 or Agency) 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 Center for Drug Evaluation and Research (CDER) is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-

the-counter drugs (OTC). CDER's drug regulatory responsibilities include premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotion activities; review, monitoring, and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

The Office of Pharmaceutical Quality (OPQ) oversees and coordinates the overall regulation of human pharmaceutical quality within CDER, including submission review, manufacturing facility assessment, and surveillance of the quality of marketed pharmaceutical products.

The Office of Testing and Research (OTR) plans and conducts pharmaceutical and biomedical research and testing; develops regulatory scientific standards involving applied pharmacology, pharmaceutical analysis, and product quality research; formulates policy, plans, and evaluates programs including oversight of the product quality and pharmacological aspects of pharmaceutical and biomedical research and testing pertaining to CDER's regulatory mission.

Duties/Responsibilities

The Deputy Office Director serves as a primary advisor to the Office director. Collaborates with the Office Director, provides leadership, program direction, and general supervision and administrative oversight for OTR's operations and all processes associated with the laboratory research on manufacturing, formulation, and characterization of drugs that supports the quality review, inspection, quality standard and policy development, education, and response activities.

- Collaborates with the Office Director to formulate and develop short-term and long-range goals to support drug quality research which includes planning, managing, organizing, and directing all of the OPQ's quality research functions and activities.
- Oversees the effective operation of the Office, provides advice and assistance concerning administrative and technical matters pertaining to the programmatic and informatic support of laboratory research.
- Provides scientific and technical expertise in matters related to the laboratory management and research on quality aspects of drug substances or drug products.
- Provides authoritative advice on scientific and technical matters associated with manufacturing and/or characterization of pharmaceuticals.

Supervisory Responsibilities: Assists in managing multi-disciplinary program, providing leadership and management oversight to subordinate support staff and division directors. Supervises and evaluates staff who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision 25 percent or more to the subordinate supervisors and staff performing the work and functions of the organizational unit. Reviews and approves or disapproves subordinate supervisor's and staff's leave requests. Obtains resources and identifies strategic objectives for the organization.

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/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.

In order 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:

Chemistry: Degree: physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics.

Or a combination of education and experience – course work equivalent to a major as shown above, including at least 30 semester hours in chemistry, supplemented by mathematics through differential and integral calculus, and at least 6 semester hours of physics, plus appropriate experience, or additional education. Please review the entire Individual Occupational Requirement (IOR) to confirm the minimum education requirements in the following link. [Chemist, 1320.](#)

Biology: Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

Or a combination of education and experience - Courses equivalent to a major, as shown above, plus appropriate experience or additional education. [Biologist, 401](#)

Chemical Engineering: Degree: Engineering. To be acceptable, the program must: (1) lead to a bachelor's degree in a school of engineering with at least one program accredited by Accreditation Board for Engineering and Technology (ABET); or (2) include differential and integral calculus and courses (more advanced than first-year physics and chemistry) in five of the following seven areas of engineering science or physics: (a) statics, dynamics; (b) strength of materials (stress-strain relationships); (c) fluid mechanics, hydraulics; (d) thermodynamics; (e) electrical fields and circuits; (f) nature and properties of materials (relating particle and aggregate structure to properties); and (g) any other comparable area of fundamental engineering science or physics, such as optics, heat transfer, soil mechanics, or electronics.

Or a combination of education and experience -- college-level education, training, and/or technical experience that furnished (1) a thorough knowledge of the physical and mathematical sciences underlying engineering, and (2) a good understanding, both theoretical and practical, of the engineering sciences and techniques and their applications to one of the branches of engineering. The adequacy of such background must be demonstrated by one of the following:

1. Professional registration or licensure: Current registration as an Engineer Intern (EI), Engineer in Training (EIT)¹, or licensure as a Professional Engineer (PE) by any State, the District of Columbia, Guam, or Puerto Rico. Absent other means of qualifying under this standard, those applicants who achieved such registration by means other than written test (e.g., State grandfather or eminence provisions) are eligible only for positions that are within or closely related to the specialty field of their registration. For example, an applicant who attains registration through a State Board's eminence provision as a manufacturing engineer typically would be rated eligible only for manufacturing engineering positions.
2. Written Test: Evidence of having successfully passed the Fundamentals of Engineering (FE)² examination or any other written test required for professional registration by an

engineering licensure board in the various States, the District of Columbia, Guam, and Puerto Rico. [Chemical Engineering, 893](#)

Desired Professional Experience:

- Demonstrated ability to formulate, develop, and implement office-wide policies, objectives, and goals.
- Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.
- Ability to identify the internal and external politics that impact the work of the organization. Perceives organizational and political reality and acts accordingly.
- Demonstrated ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative solution; makes recommendations.
- Expert ability to communicate and work with staff at all levels of the organization and varying levels of domain expertise; excellent listening skills, and a commitment to communicate in a timely manner.
- Demonstrated success in implementing information management systems that effectively meet business needs.
- Ability to organize time effectively, determine priorities, and move work forward. Advanced knowledge of regulatory policies and procedures related to the regulation of pharmaceutical quality.
- Demonstrated ability developing, mentoring, and coaching staff towards optimal performance.

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

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

All qualified candidates should submit resume or curriculum vitae with cover letter and unofficial transcripts (if you have foreign transcripts please submit foreign transcript evaluation from an accredited company) by October 21, 2021 to: OPQ_Cures_Recruitment@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 OPQ_Cures_Recruitment@fda.hhs.gov. Please reference Job Reference ID: **Deputy Office Director, OTR**

Announcement Contact

For questions regarding this Cures position, please contact Dominique Mitchell, Supervisory Administrative Officer, via email at Dominique.Mitchell@fda.hhs.gov.

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

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