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 Pharmaceutical Quality (OPQ)

Application Period: October 28, 2022 – November 07, 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.

Commissioned Corp Officers are eligible to apply.

Position: Interdisciplinary Engineer

Series: AD-0801/0806/0830/858/0893

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

Salary: Starting at:
$74,950 (Band A)
$89,834 (Band B)
$106,823 (Band C)

Work Schedule: Full Time

Cures Band(s): Band A, Band B, & Band C

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 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) conducts laboratory research on manufacturing, formulation, and characterization of drugs, and provides advice/consults, collaborative research opportunities, and scientific training to FDA staff on pharmaceutical quality, pharmaceutical equivalency, and bioavailability/bioequivalence issues including manufacturing, formulation, analytical testing, and modeling.

Duties/Responsibilities

As **an Interdisciplinary Engineer**, the incumbent serves on multi-disciplinary scientific teams providing technical leadership and guidance in research designed to resolve specific scientific issues to support regulatory assessment, policy development, and decisions.

- Provides advice concerning research activities that include the characterization of drug substances and drug products, their formulation and manufacturing processes as related to drug delivery, in vitro drug release and in vivo drug performance.
- Advises on product quality research focused on industrial pharmacy, physical chemistry, medicinal chemistry, synthetic organic chemistry, and/or macromolecular chemistry that applies to pharmaceutics; excipients function and characterization; kinetics and mechanisms of the chemical instability of drugs; kinetics and mechanism of the physical instability of dispersed and colloidal drug formulations.
- Reviews and evaluates a broad range of biopharmaceutical and chemical data which are related to sections of submissions pertaining to the chemistry, manufacturing processes, and controls in a variety of drug applications including, but not limited to Investigational New Drug Applications (INDs), New Drug Applications (NDAs), and Abbreviated New Drug Applications (ANDAs).
- Participates in the inspection of pharmaceutical manufacturing facilities applying detailed and diversified knowledge in engineering to develop standards for the analysis and evaluation of the control of production, service operations, and systems.
- Conducts system analysis using advanced data analysis or other specialized techniques to assess and mitigate product design and manufacturing risks related to ensuring product quality of pharmaceuticals.
- Preforms research to support the development of scientific standards on the composition, quality, safety, and effectiveness of drug products, including research to

facilitate the assessment and adoption of emerging technologies.

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:
Industrial Engineer, AD-0808/0806/0830/0858/0893 Series

General Engineer Series, 0801
Materials Engineer Series, 0806
Mechanical Engineer Series, 0830
Bioengineering and Biomedical Engineering Series, 0858
Chemical Engineer Series, 0893

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify:

GS-800 individual occupational requirements for Professional Engineering Positions

Qualifying Experience:
Our ideal candidate will possess:
In addition, the professional engineering experience required is defined as non-routine engineering work that required and was characterized by (1) professional knowledge of engineering; (2) professional ability to apply such knowledge to engineering problems; and (3) positive and continuing development of professional knowledge and ability.

- Professional knowledge of engineering is defined as the comprehensive, in-depth knowledge of mathematical, physical, and engineering sciences applicable to a specialty field of engineering that characterizes a full 4-year engineering program leading to a bachelor's degree, or the equivalent.
- Professional ability to apply engineering knowledge is defined as the ability to (a) apply fundamental and diversified professional engineering concepts, theories, and practices to achieve engineering objectives with versatility, judgment, and perception; (b) adapt and apply methods and techniques of related scientific disciplines; and (c) organize, analyze, interpret, and evaluate scientific data in the solution of engineering problems.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Professional Experience:
Our ideal candidate will possess:

- Ability to advise others in the application of Agency rules, regulations, and procedures.
- Ability to identify problems, gather information, draw conclusions, recommend solutions, prepare papers and reports for publication, provide advice to other scientists, and negotiate acceptance and implementation of recommendations.
- Experience developing research projects to fill gaps in knowledge related to engineering.
- Experience designing, developing, and validating the review protocols to evaluate the pharmacology of regulated compounds such as drugs or chemicals.
- Experience evaluating vitro characterization studies of product performance.

- Experience utilizing written and oral communication techniques to generate reports, as well as present findings and recommendations using scientific terms.
- Experience interacting, establishing, and maintaining effective relationships with customers, information sources, and multi-disciplinary team members.
- Experience implementing laboratory or pilot plant research projects related to product quality involving unit operations, measurement systems, and automation.
- Ability to apply sound judgement regarding their decision and/or evaluation of drugs, chemicals, and toxic agents.

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

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

All qualified candidates should submit their resume with cover letter and unofficial transcripts (if you have foreign transcripts please submit a course-by-course foreign evaluation from an accredited company (NACES or AICE) by **November 07, 2022** to: OPQOTRRecruitment@fda.hhs.gov. **Please reference Job Reference ID:** OTR Interdisciplinary Engineer

How You 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 Dominique.Mitchell@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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