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 Testing and Research (OTR)
Division of Product Quality Research (DPQR)

Application Period: March 8, 2022 – March 15, 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: Division Director
(Supervisory Interdisciplinary Scientist)

Series: AD-1320/0893

Location(s): Silver Spring, MD

Salary: Starting at $168,914

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

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.

The Division of Product Quality Research (DPQR) conducts research to evaluate the product and process design and their impact on product quality, develops in vitro test systems and quantitative analysis procedures for product quality assessment, and evaluates of emerging technologies (e.g., novel drug delivery systems) to inform a regulatory risk-based framework for quality assessment.

Duties/Responsibilities

As the **Division Director**, the incumbent plans, manages, organizes, and directs all laboratory functions and activities of the Division as carried out by highly trained and skilled staff of scientific professions.

- Oversees scientific activities of all branches within the Division; leads lab chiefs and scientists who conduct experiments to understand the impact of changes in specification of drug substance and ingredients, formulation, packaging, manufacturing equipment, and processes on product quality attributes.
- Prioritizes projects and programs based upon the degree of risk to product quality and public health impact.
- Oversees and participates in an active research program and/or directs research scientists engaged in a broad range of pharmaceutical quality research designed to ensure drug quality, safety, and efficacy.
- Provides input into the scope, status, and priority of scientific issues related to drug delivery systems, chemistry and stability, manufacturing science, biotechnology, and biopharmaceutics.

Supervisory Responsibilities**:** Manages functional discipline, providing leadership and

management oversight to subordinate staff. Supervise and evaluates staff of branch chiefs who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff performing the work and functions of the organization unit. 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.

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, AD-1320 Series

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 with course work equivalent to a major listed 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.

Chemical Engineering, AD-0893 Series

A. 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 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 relationship); (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

B. 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.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Education: Master's degree or higher in physical sciences, life sciences, or chemical engineering.

Desired Professional Experience:

Our ideal candidate will possess:

- Expert experience in leading and overseeing senior level lab scientists who conduct experiments which bare a major impact on changes in specification of drug substance and ingredients, formulation, packaging, manufacturing equipment, and processes on product quality attributes.
- Successful performance requires a multi-disciplinary knowledge of drug chemistry and chemical engineering, broad experience, knowledge, and thorough understanding of the relation to drug delivery systems, chemistry and stability, manufacturing science, biotechnology, and biopharmaceutics.

- Providing support of systems engineering, technical and logistical activities performed in the systems engineering integration and test section.
- Demonstrated skill in applying leadership principles and concepts.
- Must possess the ability to adept precedents from previous approaches to similar projects in order to provide for specialized requirements of some projects. Uses sound judgment and perception in all aspects of work, applying versatility, initiative, and innovation to complete tasks applying principles learned from other assignments as applicable.

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

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 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 foreign transcript evaluation from an accredited company) by **March 15, 2022,** to: OPQOTRRecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring officials 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 OPQOTRRecruitment@fda.hhs.gov. Please reference job code: **OTR Division Director.**

Announcement Contact

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

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