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 and Research (DPQR)

Position: Supervisory Interdisciplinary Scientist (Lab Chief)

Series: AD – 1320/893

Location(s): Silver Spring, MD

Travel Requirements: 25% or less

Application Period: January 6, 2021 – January 12, 2021

Salary: Starting at $121,316 (Cures Band D)

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: Relocation expenses will not be paid.

Special Notes: This position is being filled under an excepted 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 compensated under the provisions of the authority. Additional information on 21st Century Cures Act can be found here.

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 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 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 prediction, and evaluates emerging manufacturing technologies to inform a regulatory risk-based framework for quality assessment.

Position Summary:

As **Supervisory Interdisciplinary Scientist (Lab Chief)**, the incumbent plans, manages, organizes, and directs all laboratory functions and activities carried out by the Branch. The incumbent interacts with a staff, consisting of 8-12 highly technical scientific professionals with extensive pharmaceutical analysis knowledge of the quality assessment of pharmaceutical products.

Supervisory responsibilities:
Provides leadership and management oversight to subordinate staff. Supervises and evaluates staff 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 organizational unit. Obtains and identifies strategic objectives for the organization.

Duties/Responsibilities:

- Manages scientists who evaluate drug delivery systems, biopharmaceutics and chemistry and stability issues in human drug products
- Collaboratively participates in decision making processes, meetings, and discussions and fully engages in actual determination, allocation, and administration of the program segment, functions, and activities of the Lab
- Prioritizes projects and programs based upon the degree of risk to public health. Assumes responsibility for ensuring that data and reports are consistent with office requirements and existing policy, and that adequate scientific review has been completed
- Provides input into the scope, status, and priority of scientific issues related to product and process variability affecting the critical quality attributes of drug products
- Develops manufacturing process understanding and help develop performance

standards and validates methods designed to enhance the Center's programs and the scientific/professional competencies of Division staff
- Continuously reviews state-of-the-art scientific activities to identify and integrate the most advanced and evolving research theories and/or practices in spectroscopy, analytical, bioanalytical, and chemometrics science into the Center's drug regulatory programs
- Oversees and participates in active research and testing programs and/or directs laboratory scientists engaged in a broadrange of pharmaceutical quality research and testing designed to ensure drug safety and efficacy
- Maintains and promotes in-house training and quality assurance programs with comply with agency regulations for research, and all internal standard operating procedures. Provides leadership and direction in strengthening the operation and scientific management of the Division

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.

Click here for more information on Equal Employment Opportunity (EEO) for federal employees & job applicants

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.

Professional Experience/Desirable Qualifications AD-893/1320:

To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the level of the position. Qualifying experience involves possession of significant experience in identifying, articulating, addressing, and resolving unique, far-reaching, and/or previously unresolved and precedent-setting problems and complex issues involved in and arising from the planning and conducting of pharmaceutical quality research.

- Knowledge of regulatory assessment process and project management skills
- Demonstrated ability to conduct research in the area of advanced analytics for pharmaceuticals
- Master's degree or higher in chemical engineering, chemistry, physical sciences or life sciences
- Demonstrated ability to identify the internal and external policies that impact the work of the organization. Perceives organizational and political reality and acts accordingly
- Demonstrated ability to implement internal practices and procedures to support quality management, continuousimprovement, and safety of laboratory operations
- Demonstrated ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative decisions; makes recommendations
- Success experience in organizational change management
- Expert ability to communicate, verbally and in writing, 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

Key requirements will include:

Desirable Education:

Chemistry, 1320: 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. Chemistry, 1320

Chemical Engineering, 893: 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

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
    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 the following:

- A thorough knowledge of the physical and mathematical sciences underlying engineering
- 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), 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.

3. Specified academic courses: Successful completion of at least 60 semester hours of courses in the physical, mathematical, and engineering sciences and that included the courses specified in the basic requirements. The courses must be fully acceptable toward meeting the requirements of an engineering program.
4. Related curriculum:Successful completion of a curriculum leading to a bachelor's degree in an appropriate scientific field, e.g., engineering technology, physics, chemistry, architecture, computer science, mathematics, hydrology, or geology, may be accepted in lieu of a bachelor's degree in engineering, provided the applicant has had at least 1 year of professional engineering experience acquired under professional engineering supervision and guidance. Ordinarily there should be either an established plan of intensive training to develop professional engineering competence, or several years of prior professional engineering-type experience, e.g., in interdisciplinary positions. (The above examples of related curricula are not all-inclusive.) Chemical Engineering, 893

Conditions of Employment:

1. Security Clearance:

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 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.

2. Ethics Requirements:

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

3. How to Apply:

All qualified candidates should submit a curriculum vitae and cover letter describing why you are uniquely qualified for this position and unofficial transcripts including how you possess the

desired experience and qualifications identified above (if you have foreign transcripts please submit foreign transcript evaluation from an accredited company), , electronically by **January 12, 2021** to OPQ_Cures_Recruitment@fda.hhs.gov. Candidate resumes may be shared with the hiring official in CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share." For questions please contact Dominique Mitchell, Supervisory Administrative Officer, via email at Dominique.Mitchell@fda.hhs.gov. Please reference Job Code: **Supervisory Interdisciplinary Scientist, DPQR.**

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