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 Pharmaceutical Manufacturing Assessment (OPMA)
Division of Biotechnology Manufacturing

Position: Supervisory Interdisciplinary Scientist (Division Director)

Series: AD - 1320/403/401

Location(s): White Oak, Silver Spring, MD

Travel Requirements: Up to 25%

Application Period: May 11, 2020 – May 22, 2020

Salary: Starting at $162,339

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 paid under the provisions of the authority.

Additional information on 21st Century Cures Act can be found here.

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 safe, and effective.

The Center for Drug Evaluation and Research is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs. 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 Manufacturing Assessment (OPMA) serves as the Office of Pharmaceutical Quality's (OPQ) centralized resource on pre-and post-approval inspections and manufacturing issues that impact application assessment, and the Division of Biotechnology Manufacturing (DBM) supports this by overseeing microbial control, sterility assurance, and microbial product quality aspects for biologics manufacturing, and on inspectional and facilities activities related to pre-license, pre-approval and post-approval inspections, and other post-marketing/compliance activities.

Position Summary:

As Division Director, the incumbent provides the scientific and technical expertise and managerial leadership pertaining to the scientific review and quality evaluation of the microbiological and manufacturing process data for Investigational New Drugs (INDs), Biologics License Applications (BLAs), Drug Master files (DMFs), and supplemental BLAs assigned to the division.

Supervisory responsibilities: Manages the functional discipline, providing leadership and management oversight to subordinate staff. Supervises 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 organizational unit. Obtains and identifies strategic objectives for the organization.

Duties/Responsibilities:

- Directs the operational management of the division, monitors the quantity and quality of work performance outcomes, initiates corrective action to solve and prevent backlogs and procedural difficulties.
- Provides leadership and participation on the leveraging of microbiological and manufacturing process data to identify and monitor leading indicators of potential quality problems that impact application assessments, product availability, and consumer safety.
- Provides leadership and guidance to the division on matters related to pre-license and/or pre- and post-approval inspections, and post-marking/compliance of the

microbiological manufacturing process facilities.

- Manages, leads, develops, and executes the strategies and processes involving the pre-license and/or pre-approval biotechnology-related inspection assignments and facilities evaluations to ensure the implementation of Current Good Manufacturing Practices (CGMP) and to determine conformance with pre-license and/or pre-approval inspection program requirements.
- Collaborates with leadership to formulate and develop short-term and long-range pre-license and/or pre- and post-approval inspection and manufacturing assessment program goals, policies, and standards.

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 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:

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 enforcing laws and regulations to protect consumers from drugs that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.

- Possession of significant experience in identifying, articulating, addressing and resolving unique, far-reaching and/or previously unresolved and precedent-setting problems and complex issues
- Demonstrated skill in applying leadership principles and concepts; managing and leading a diverse interdisciplinary staff
- Excellent communicator with strong interpersonal skills
- Significant experience in managing large organizations with a regulatory mission, including a demonstrated ability:
    - Produce results and lead change
    - Lead people
    - Build coalitions and collaborate across boundaries to achieve common goals
- Demonstrated ability to identify and analyze complex problems, generate and evaluate alternative solutions, and make evidence-based decisions

Key requirements will include:

Desirable Education:

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 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 IOR to confirm the minimum education requirements in the following link. Chemist, 1320

Degree: microbiology; or biology, chemistry, or basic medical science that included at least 20 semester hours in microbiology and other subjects related to the study of microorganisms, and 20 semester hours in the physical and mathematical sciences combining course work in organic chemistry or biochemistry, physics, and college algebra, or their equivalent. OR Combination of education and experience – courses equivalent to a major in microbiology, biology, chemistry, or basic medical science that included courses shown above, plus appropriate experience or additional education. Please review the entire IOR to confirm the minimum education requirements in the following link. Microbiologist, 403

Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the positions. OR Combination of education and experience – course work equivalent to a major show above, plus appropriate experience or additional education. Please review the entire IOR to confirm the minimum education requirements in the following link. Biologist, 401

Conditions of Employment:

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.

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.

How to Apply: All qualified candidates should submit a curriculum vitae and cover letter describing why you are uniquely qualified for this position, including how you possess the desired experience and qualifications identified above, electronically by May 22, 2020 to: OPQ_Cures_Recruitment@fda.hhs.gov. For questions please contact Dominique Mitchell,

Supervisory Administrative Officer, via email at Dominique.Mitchell@fda.hhs.gov. Please reference Job Code: Division Director, DMA.

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