TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Tissues and Advanced Therapies (OTAT)
Division of Regulatory Project Management (DRPM)
Regulatory Management Staff I & II

Position: Supervisory Regulatory Project Health Manager (Staff Chief)

Series: 601

Location(s): Silver Spring, Maryland

Travel Requirements: 25%

Application Period: September 4, 2020 – September 18, 2020

Salary: Starting at $121,316

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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 Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA), Office of Tissues and Advanced Therapies, Division of Regulatory Project

Management, is recruiting two Supervisory Regulatory Project Health Managers (Branch Chief's) to serve as supervisors and technical authority for administrative and regulatory screening of all products regulated by the Office.

CBER is a Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. CBER protects and advances the public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

Position Summary:

The Branch Chief within the Center for Biologics Evaluation and Research/Office of Tissues and Advanced Therapies/Division of Regulatory Project Management/Regulatory Project Management Branch reports directly to the Director, Division of Regulatory Project Management. The incumbent serves as the supervisor and is the technical authority for administrative and regulatory screening of all products in the biological licensing area regulated by the Office.

Supervisory responsibilities:

- Supervises the work of employees graded through GS 14. Assigns functional work to subordinates and directs the assigned functions and activities. Performs supervisory checks and provides supervision as deemed necessary to ensure that work progresses satisfactorily. Keeps employees informed of management goals and objectives.
- Defines technical work requirements and milestones; evaluates the organization and employee accomplishments by accepting or rejecting work products; and presents and defends organization and employees work to senior management and other offices.
- Oversees the Performance Management program, including establishing standards of performance and evaluating staff against performance standards that assess and reward employee performance based on organizational goals and values;
- Obtains resources and identifies strategic objectives for the organization.
- Addresses grievances, taking disciplinary measures such as warnings, reprimands, suspensions and removals and other appropriate action to promote the efficiency of the Branch, approving or disapproving leave requests from the staff under his or her supervision, and being accountable for the Labor/Management Relations program within the Branch.
- Initiates requests for filling vacancies, revising position structure, or establishing additional positions to meet workload requirements. Serves on hiring panels, selects and hires subordinate employees for the Branch. Prepares or makes

recommendations for personnel actions including reassignments, promotions, details, etc.

- Develops training plans for employees and recommends employees for formal training courses. Implements provision of depot programs in area of equal opportunity, employee management, suggestions program etc. Periodically reviews job descriptions of subordinates for ensuring being current and accuracy; reports detailing of employees to jobs other than their own; initiates or participates in review and improvement of work methods, organization features, and the structuring of positions to eliminate unnecessary ones and achieve optimum content in those remaining.
- Provides equal opportunity in all Federal human capital and employment programs regardless of race, color, gender, national origin, religion, age, disability, genetic information, sexual orientation, affiliation or non-affiliation with a labor organization, political affiliation, status as a parent or gender identity.
- Provides employees resources and information that insures a safe and healthy work environment.
- Performs technical duties that includes identifying, articulating, addressing and resolving unique, far- reaching and/or previously unresolved and precedent-setting problems and complex issues relating to Investigational new drug applications (INDs), investigation device exemptions (IDEs), biologics license applications (BLAs), New Drug Applications (NDAs), Premarket Notifications (510ks) and premarket approvals (PMAs).
- Analyzes, evaluates, and consults in making final decisions that become accepted Office policy and procedures.
- Provides expert advice based on expert regulatory assessments and consultations to the Directors, OTAT and CBER.
- Reviews, initiates and drafts revisions and technical corrections to new and existing regulatory documents on complex regulatory issues. These regulations and policy statements are broad in scope and generally affect the full range of INDs, IDEs, NDAs, and BLAs that are regulated by the Office. Reviews and edits every letter and meeting documents for their direct reports before being issued.
- Utilizes extensive expertise and knowledge regarding FDA program regulatory compliance policy principles and techniques and is familiar with FDA-wide and Center missions, functions, organizations, methods and procedures.
- Reviews, analyzes, and recommends improvements in product development program policies, reports, records, correspondence and communications.
- Develops, interprets, and analyzes complex documents related to the FDA regulatory and product development program policy activities and providing recommendations or options to CBER management.
- Develops program policy plans and procedures governing relationships with key FDA staffs.
- Determines action required to enhance improvements and mutually beneficial changes,

works with groups of multi- disciplinary profession.
- Represents and speaks for the Office at national and international meetings and forums.
- Represents the Office on policy-related problems and issues pertaining to OTAT programs in meetings with counterpart government agencies, health professionals, and foreign officials.
- Participates in intra/inter- Agency task forces, and/or regulatory working groups. The work significantly impacts the work of regulated industry, other Federal agencies, state, local and foreign governments, professional organizations, public interest groups, and the general public.

Duties/Responsibilities:

Incumbent is responsible for directing the work of the branch, assigning incoming documents and providing first level signoff for outgoing documents; responsible for providing review on draft guidance documents and regulations; participates in and leads regulatory projects; responsible for drug assessments and regulatory mandates; directs and supports implementation of new laws and regulations; and provides technical and non-technical guidance to internal and external senior level officials and stakeholders.

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:

- Ability to provide leadership and direction of a technical staff involved in the regulation of biological products;
- Experience performing review of technical or complex regulatory information regarding biological products in accordance with applicable laws and regulations;
- Experience providing advice and assistance to senior management in developing and implementing regulatory policy and guidance;
- Strong oral and written communication skills; and,
- Deep analytical skills recognizing organization strategy and business process.

Key requirements will include:

Education: 0601 Series
Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained.

Evaluation of Experience for Grants Administration Positions:
For positions at grades GS-12 and above involved in professional work in grants administration, qualifying experience is considered to be experience in grants administration in areas of science, medical and healthcare fields similar or related to the work of the position. Such experience must have involved professional judgment of a kind and level of difficulty and responsibility essential to successful performance in the position to be filled.

Conditions of Employment:

Security Clearance:

Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. All information concerning qualifications is subject to investigation.

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 may 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: Please submit resume or curriculum vitae with cover letter by September 18, 2020 to: CBERHumanCapital@fda.hhs.gov. Please reference Job Information **CURES-20-01** in the subject line of your email.

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

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