Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products (OTP)

Application Period: November 14, 2022 – January 14, 2023.

Area of Consideration: The Public

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.

Position: Super Office Director

Series: 0602 (Physician)

Location(s): Silver Spring, MD

Salary Range: $250,000 - $355,870 and is set to commensurate with education and experience.

Work Schedule: Full Time

Cures Band(s): Band H

Full Performance Band Level: Band H

Travel Requirements: 25% or less

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 compensated 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 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 are safe, and effective.

The mission of the Center for Biologics Evaluation and Research (CBER) is to protect and enhance the public health through the regulation of biological and related products by ensuring that these products are safe and effective and available to those who need them. Biological products often represent cutting-edge biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have few or no other treatment options.

The Office of Therapeutic Products (OTP) is a newly established Super Office within CBER. The mission of OTP is to is to promote public health through a data-driven process to provide regulatory oversight that helps ensure medical products are safe and effective. OTP oversees development and regulation for a wide variety of products, including cells, tissues, and gene therapies, protein products derived from blood and their recombinant analogues, along with certain medical devices used in the production of these products. In addition to regulatory review of product quality, safety and effectiveness, the Super Office conducts applied scientific research related to the products that it regulates, contributes to the development of relevant regulatory policy, and supports other agency and center components involved in ensuring compliance with agency biologics regulations.

Duties/Responsibilities

As the Super Office Director of OTP in CBER, the incumbent provides executive leadership to the six offices within the Super Office and to the Immediate Office of the Director (IOD) regarding the review of regulatory submissions for quality, safety and effectiveness, for the conduct of applied scientific research and relevant regulatory policy. Manages highly complex and difficult assignments of national and international scope and significance, as well as additional related duties as noted below.

- Oversees the various offices and programs within the Super Office, which involves applying a science-based approach in support of regulatory decision-making regarding clinical applications, the conduct of applied scientific research, and the development of regulatory policy; supports compliance and enforcement activities related to regulated products; collaborates with other Center and Agency units requiring expertise in therapeutic product evaluation.
- Supervises the various Office Directors and the Immediate Office in planning, managing, organizing, and directing regulatory review operations, and research activities of the Super Office as carried out by the Office Directors and highly trained and skilled staff (Immediate Office and support staff).
- Leads, prepares, coordinates, and attends critical sponsor/internal meetings, supports, and promotes leadership, management, and reviewer development.
- Advances new policy initiatives related to regulated products, proposing and developing guidance, changes in regulations, and legislative initiatives, as appropriate, based on the emerging science.
- Directs the implementation of new laws and regulations which affect the mission of the Super Office including initiating and implementing new policies, systems, procedures, and organizational structures.
- Develops and implements Super Office policies and plans, makes critical decisions, and provides expert advice and counsel on cost-effective use of all resources including budget and manpower.
- Oversees the development of core competencies of review staff in the Super Office to maintain and render outstanding regulatory review, advice, policy, and publications and is responsible for identifying new scientific initiatives.
- Applies administrative and program management principles and skills to carry out the mission of the Super Office and addresses and solves challenging and often precedent- setting problems. Seeks and develops the most cost effective and fiscally responsible methods to manage and lead day to day operations.
- Represents the Super Office in dealing and negotiating with individuals representing organizations such as the Congress; other Federal agencies; State, local, and foreign governments; the regulated industry; and professional societies.
- In consultation with the Center Director, initiates and participates fully in discussions and decisions concerning Super Office plans, programs, and activities, both in strategic planning and implementation. Provides authoritative advice and assessments of the impact of actual and proposed Administration or Congressional actions on the program segments, functions, and activities of the division.
- Serves as subject matter expert and is a recognized authority and senior level expert

Supervisory Duties:

Organizational Management: Manages a Super Office currently with less than 500 positions.

Program Management: Runs two or more multi-disciplinary programs in the Center. Identifies high-level activities needed to achieve desired outcomes. Shares in the strategic oversight and implementation of Center goals in collaboration with the Center Director.

Resource Management: Monitors and reports on resources needed to run a Super Office or one or more portfolios in the Center.

Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Identifies organizational capability gaps.

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.

In order 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:

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: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Desired Education

The ideal candidate should possess a medical degree from an accredited institution and potentially another research doctoral degree such as a Ph.D. or one widely recognized in U.S. academe as equivalent to a Ph.D.

Professional Experience:

Our ideal candidate will possess:

- Ability to provide visionary leadership for a scientific and technical program.

- Ability to manage a diverse workforce of scientific and technical professions.
- Ability to evaluate the quality, safety, and effectiveness of biologic products based.
- Ability to develop regulatory policy initiatives related to medical products.
- Ability to function within a regulatory environment and problem solve to meet challenging demands.
- An understanding of Federal Regulations related to the work of the Center for Biologics Evaluation and Research.
- Prior senior leadership experience and excellent interpersonal skills.

Desired Professional Experience:

- Provides scientific and technical leadership, direction, and supervision to a multidisciplinary scientific, engineering, and medical science staff.
- Provides expert technical and scientific guidance/assessment to senior leadership on complex, precedent setting, and/or controversial issues involving policies related to cellular, tissue gene therapy (including viral and non-viral vectors), therapeutic vaccines, and plasma-derived and coagulation products as well as associated medical devices.
- Knowledge and understanding of the provisions, limitations, and practical applications of FDA issues, policies, laws, and regulations related to cellular, tissue gene therapy (including viral and non-viral vectors), therapeutic vaccines, and plasma-derived and coagulation products as well as associated medical devices.
- Collaborates with other scientific, technical, and regulatory staff to develop and implement policy initiatives related to cellular, tissue gene therapy (including viral and non-viral vectors), therapeutic vaccines, and plasma-derived and coagulation products as well as associated medical devices.
- Ability to communicate complex scientific concepts to a diverse audience (examples include, policy makers, manufacturers, scientists, universities, and the public).

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: 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.

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:

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:

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:

Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), copy of your unofficial transcripts (if applicable), copy of your active medical license/s (if applicable), copy of your board certification/s (if applicable), SF50 (if applicable), latest signed PMAP (if applicable), and letter of interest with ***"CURES CBER/OTP Super Office Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **January 14, 2023.**

Announcement Contact:

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

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

FDA is an equal opportunity employer.