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 Therapeutic Products (OTP)

Application Period: October 3 – December 2, 2022

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: 0401, 0403, 0601, 0602

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

Salary: Series 0401, 0403, 0601 = Table 1 - Starting at $247,369 and is set to commensurate with education and experience.
Series 0602 = Table 3 - Starting at $250,000 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

Bargaining Unit: 8888

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 is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

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 including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

Duties/Responsibilities:
The incumbent serves as the Super Office Director for the Office of Therapeutic Products (OTP) under the Center for Biologics Evaluation and Research (CBER) and manages the Super Office. This position reports to the Director of

CBER. The Super Office Director oversees the planning, development, and direction of strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's cellular, tissue, gene therapy (including viral and non-viral vectors), therapeutic vaccines, and plasma-derived and coagulation products as well as associated medical devices.

Specifically, the Office Director will:

- Advise the Center Director and other officials on the Food and Drug Administration's (FDA) regulatory and enforcement responsibilities and possible risks.
- Implement programs and projects to identify, assess, and prioritize the public health significance and patient risk regarding safety concerns.
- Lead and oversee the development of products enforcement and compliance policy and standards and contributes to the planning and development of compliance and enforcement strategies and actions that are patient-focused and risk-based to secure safety, efficacy, and quality.
- Execute high-level decisions, monitor performance, and direct strategies and operations of component Offices to ensure compliance and enforcement decisions and policies are patient-focused and risk-based.
- Design and develop internal procedures and processes to support work quality and provides oversight of implementation, monitoring, and continual improvement of the quality system.
- Develop, coordinate, and implement post-market risk assessment policies, guidance, and interpretations and, when appropriate, initiates the development or enhancement of regulations.

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:

Candidates would ideally have a graduate degree or higher (i.e., Masters, J.D., Ph.D., and/or M.D.).

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 **December 2, 2022**.

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.