**Title 21 Vacancy Announcement**
**Project Manager**
**Department of Health and Human Services (HHS)**
**Food and Drug Administration (FDA)**
**Center for Biologics Evaluation and Research (CBER)**
**Office of Therapeutic Products (OTP)**
**Immediate Office of the Director**

Summary:

The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Office of Therapeutic Products (OTP), Immediate Office of the Director (IOD). This position is being filled under a streamlined hiring authority, 21 US Code 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

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.

Overview

Opening & Closing Dates: July 31, 2024 through August 19, 2024

Salary: Starting at $117, 962

Pay Scale & Grade: AD-0301

Location: Silver Springs, MD

Remote Job No

Telework Eligible: Yes – as determined by agency policy

Travel Required: 25% or less

Relocation Expenses Reimbursed

**Application Period:** July 31, 2024 through August 19, 2024

**Area of Consideration:** 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:** Project Manager

**Series:** 0301

**Location(s):** Silver Spring, MD

**Salary:** Starting at $117, 962

**Work Schedule:** Full Time

**Title 21 Pay Table & Band:** Table 7 & Band C

**Full Performance Band Level:** Band C

**Travel Requirements:** 25% or less

**Bargaining Unit:** 3591

**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 Center for Biologics Evaluation and Research (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's mission 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. CBER protects and advances the public health by ensuring that biological products are safe, 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.

## Duties/Responsibilities

The incumbent serves as a Project Manager for the Immediate Office of the Director under the Office of Therapeutic Products (OTP) and coordinates and integrates the planning, programming, scheduling, and overall management for OTP projects. This position reports to the Deputy Super Office Director. OTP is a newly established Super Office within CBER which is responsible for the continued safety, purity, potency, and effectiveness of cellular, tissue, and gene therapies and other products regulated by OTP. The incumbent works collaboratively to develop strategic project plans and associated milestones, schedule and facilitate meetings, prepare issues-based agendas and official records of meetings, and track the overall status of projects.

Specifically, the Project Manager will:

- Works with members of the OTP Management Team, Centers throught the Agency, and OTP to develop, modify, and provide input on deadlines, priority lists, project plans, and documentation, including setting timeframes, milestones, agreed upon endpoints, and final product reviews.
- Actively monitors team and project workloads, and takes appropriate steps to ensure timeliness and responsiveness.
- Monitors project activities and resources, and implements and maintains quality control assurance processes to mitigate risk, ensure timeliness, make improvements, and take corrective action when problems arise.
- Participates in the planning of operational projects and activities associated with OTP.
- Acts as a liaison to other Centers for projects under review within OTP, prioritizing OTP projects/assignments; coordinating meetings; tracking and managing cross-cutting assignments; organizing and tracking large projects and strategic initiatives.
- Assisting with managers' schedules and meetings.
- Identify issues and opportunities which would benefit from cross-collaboration among assigned program areas.
- Monitor and report the actual status of all activities within assigned projects through interaction with project participants and, if necessary, supervisors and directors.
- Advise supervisors and management of recommended solutions and potential impacts to problem areas.
- Evaluate activities across program areas to identify activities that meet the needs of targeted audiences and those that require refinement or rejection.

- Apply knowledge gained from challenges and successes in one program area across all the team activities, as appropriate.
- Develop internal procedures and processes to support quality, consistency, and continual improvement of program activities.
- Identify project activities or situations that may adversely impact project plans.
- Negotiate resolution of potential conflicts or competing priorities among program areas to avoid delays in achieving the program goals.
- The Project Manager catalogues, tracks, and assesses the external stakeholder engagement activities of the OTP regulatory staff using available FDA Information Technology (IT) platforms.
- Design and implement a sustainable operational process for capturing, tracking, and reporting current and future engagement activities utilizing FDA IT.
- Define a periodic assessment schedule for the review and refinement of the Office tracking processes.
- Perform projects or activities personally, or establish and oversees committees, work groups, or contract staff as needed, and addresses the facts or knowledge related to the issue or problem in study.

## 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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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:Scientific, Technical, and Professional Fields

1. 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:** There are no education requirements.

**Desired Education/Professional Experience:**

- Ideally the candiate would possess Bachelor's degree in a scientific or medical field, graduate degree (Master's or Doctorate).
- Program management
- Communication and/or public affairs experience preferred, but not required.
- Ability to work as a team member managing multiple long-term projects with various leads.
- Skilled at maintaining constructive working relationships.
- Expert knowledge to define complex problems, analyze alternatives, and make recommendations that significantly change, interpret, or develop important programs.
- Knowledge to recognize the impact in terms of schedule, costs, risks involved, trade-offs necessary and to use resources effectively.
- Ability to gauge the effort required to recommend next steps and contribute to long-term program planning.
- Knowledge regarding the techniques, processes, and procedures established within the FDA to review, launch, and maintain outreach projects

## 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.

## 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 resume or curriculum vitae with cover letter by August 19, 2024 to: CBERHumanCapital@fda.hhs.gov with ***"CURES CBER/OTP/IOD Project Manager"*** in the subject line. Candidate resumes may be shared with other hiring officials within the Center for Biologics Evaluation and Research (CBER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share".

## 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.*