

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 Management (OM)
Division of Management and Planning Analysis (DMPA)
Capacity Planning and Management Analysis Branch (CPMAB)

Application Period: August 2, 2023 - August 16, 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.

<u>Position:</u> Program Analyst <u>Series</u>: 0343

*Multiple selections can be made

<u>Location(s):</u> White Oak Campus, Silver Spring, MD <u>Salary:</u>

\$78,592 – \$103,984 (Band A) **Work Schedule:** Full time \$94,199 – \$127,096 (Band B)

<u>Telework Eligible</u>: Yes – as determined by agency policy

Cures Band(s): Bands A/B Full Performance Band Level (FPBL):

Band A FPBL: Band B Band B FPBL: Band B

Travel Requirements: 25% or less

Bargaining Unit: 3591

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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 (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) 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.

The Office of Management leads procedural and process changes through developing and applying new strategies to emerging problems and new management initiatives, allocating dollars and staff resources to CBER's program offices, monitoring their usage, and setting priorities to improve the level of customer service and program performance to meet CBER's goal of protecting and promoting the public health. OM directs and monitors human resources, budget, payroll, space issues, assistance on human resources, provides administrative and technical support for advisory committee meetings, as well as provides laboratory and equipment support. In supporting the mission of the agency, OM develops, maintains, and supports a high quality and diverse workforce.

Duties/Responsibilities

The incumbent serves as a Program Analyst in the Capacity Planning and Management Analysis Branch (CPMAB), Division of Management and Planning Analysis (DMPA), Office of Management (OM). This position reports to the CPMAB Branch Chief.

The Branch leads CBER's Resource Capacity Planning function in coordination with other medical product Centers at FDA; manages CBER's modernized time reporting system, which captures activity time reporting data for the Center; supports user fee activities including negotiations and providing input on the annual reports to Congress for the Prescription Drug User Fee Act (PDUFA), the Medical Device User Fee Act (MDUFA), the Generic Drug User Fee Act (GDUFA) and the Biosimilar User Fee Act (BsUFA); administers the CBER Internal Control Program which implements FDA policy and procedures in carrying out the requirements set forth in the OMB Circular A-123, Management's Responsibility for Internal Control, and identification of the Center's enterprise risks and submission of the Center's Enterprise Risk Management tool; and evaluates Center programs' effectiveness and efficiencies ensuring consistency with the overall Center philosophy and consistency with policy and management goals.

The candidate must possess experience in areas such as Budget Planning, Managerial Accounting, Program Evaluation, Strategic Planning, Performance Management, Enterprise Risk Management, Resource Management and Planning Activities, Data Analytics and Visualization, Operations Research or Management Science:

- Experience planning and conducting studies related to program and management improvement issues; and/or
- Experience gathering and organizing narrative and statistical information using, and when necessary modifying, accepted methods to suit the peculiar circumstances presented by different studies and projects; and/or
- Experience in meeting management with high-level officials to investigate facts, present conclusions, recommendations, and alternatives and to present alternate forms of action; and/or
- Experience in budget planning or execution; and/or
- Experience in program/project evaluation; and/or
- > Experience in data analytics, including advanced excel techniques, R, and/or Python; and/or
- Experience in qualitative and quantitative techniques to analyze, evaluate, and/or improve the effectiveness and efficiency of resources.

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 <u>OPM Qualification Standards</u> 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 <u>required</u> qualifications. Please note: Additional education and experience listed that is not indicated as <u>required</u> is preferable and desired. Candidates who do not meet the "desired" criteria will <u>not</u> be excluded from consideration for this position.

Desired Professional Experience:

- Adapting existing quantitative and qualitative analytical methods and techniques to specific issues and developing new approaches to resolve complex productivity problems and issues.
- Developing, coordinating, and implementing data to evaluate operations for a major organizational segment of an agency.
- Reviewing information, reconciling conflicting data, and devising new and modified methods to analyze findings.
- Interpreting findings resulting from studies that are independently developed.

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

Education Transcripts

<u>SUBMITTING YOUR TRANSCRIPTS:</u> 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.

<u>FOREIGN EDUCATION:</u> 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>U.S. Department of Education website for Foreign Education Evaluation</u>.

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 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), SF-50 (if applicable), latest PMAP (if applicable), and letter of interest with "CURES CBER/OM/DMPA/CPMAB Program Analyst" in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through August 16, 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.

