



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 Communications Outreach and Development (OCOD)
Division of Disclosure and Oversight Management (DDOM)
Access Litigation and Freedom of Information Act (FOIA) Branch (ALFOIB)

Application Period: September 28 – October 12, 2022

Area of Consideration: 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: Science Disclosure Analyst (Temporary Position NTE 1 Year) * **Series:** 0401

*Multiple selections can be made

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

Salary: Starting at \$75,950

Work Schedule: Full Time

Cures Band(s): Band A

Full Performance Band Level: Band A

Travel Requirements: Not required

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 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.

Duties/Responsibilities

The incumbent serves as a Science Disclosure Analyst within the Access Litigation and Freedom of Information Act (FOIA) Branch (ALFOIB) in the Division of Disclosure and Oversight Management (DDOM) under the Office of

Communication Outreach and Development (OCOD). This position reports to the Chief of ALFOIB. The incumbent uses scientific knowledge to implement and ensure compliance of statutory requirements for the public release of information about technical scientific information specific to applications for an array of biological products, both investigational and licensed, including allergenic, blood and blood components, medical devices and tests, gene therapy, human tissues and cellular products, vaccines, and xenotransplantation products.

Specifically, the Science Disclosure Analyst will:

- Develop segments of the Center's scientific disclosure analysis activities and review, under the direction of higher graded staff, important and sensitive Center responses to requests for Center records received under the Freedom of Information Act (FOIA) as amended.
- Review requests for scientific disclosure analysis of Center records including, but not limited to, web posting of records required by the Food and Drug Administration Amendments Act of 2007 (FDAAA), other statutes, Center policy, or records posted for advisory committee meetings and scientific disclosure analysis of Center records for sharing with international counterparts.
- Conduct the scientific disclosure analysis on records rich in advanced scientific content and apply the understanding of scientific principles, content, and context related to drug and biological products to make consistent disclosure determinations.
- Prepare Center draft recommendations for denials of requested information, which is exempt from disclosure.
- Provide advice on disclosure of advisory committee records and records for sharing with international counterparts; such recommendations include sufficient justification and all available evidence to support the recommendations.
- Provide guidance and direction to Center personnel involved with handling responses to Freedom of Information (FOI) requests and other disclosure activities. This requires an understanding of the FOIA, the Privacy Act (PA), DHHS's and FDA's implementing regulations and always requires that the incumbent keep abreast of all changes to the statutes and regulations to ensure Center compliance.
- Be aware of current developments in the Center to correctly review and analyze records for disclosure.
- Have sensitivity to emerging problems that are reflected in disclosure inquiries and assists in developing recommendations for Center action to cope with these problems. These recommendations are directed to the affected units, within the Center, through the division management. The incumbent ensures appropriate consideration and referral of such problems.
- Work with representatives from the Office of Chief Counsel in the preparation of background and testimony of FDA officials in court cases on defending FDA's position on the disclosure of requested information.

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 Professional Experience:

- General knowledge of the Food, Drug and Cosmetic Act, the Public Health Service Act, and the implementing regulations and policies;
- General knowledge of the FOIA and the PA;
- Knowledge of biological sciences related to the products regulated by CBER programs which includes fields such as biology, microbiology, medical technology, biochemistry, chemistry, clinical pharmacology, pharmacology, pharmaceutical science, immunology, and/or biostatistics, molecular biology, virology, cell biology, microbiology, genetics, physiology, and anatomy to conduct scientific disclosure analysis of Center records;
- Knowledge of Office, Center, and Agency FOIA/PA policies, programs and activities and key personnel;
- General knowledge of enforcement/compliance implications, especially with respect to Center compliance policies and programs;
- Interpersonal skills sufficient to organize and coordinate thorough, systematic and professional projects to meet the established and unanticipated needs of the CBER offices, Office of the Commissioner, other Centers, HHS and other Agencies; and
- Ability to effectively communicate orally and in writing.

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), SF50 (if applicable), latest PMAP (if applicable), and letter of interest with **"CURES CBER/OCOD/DDOM/ALFOIB Science Disclosure Analyst"** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **October 12, 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.

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