**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 Blood Research and Review (OBRR)**
**Division of Blood Components and Devices (DBCD)**
**Devices Review Branch (DRB)**

**Application Period:** May 9, 2024 – May 22, 2024

**Area of Consideration:** FDA-Wide
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:** Lead Clinical Laboratory Scientist

**Series:** 0644

**Location:** White Oak Campus, Silver Spring, MD

**Salary:** Starting at $139,395 and is set commensurate with education and experience.

**Telework Eligible**: Yes – as determined by agency policy.

**Travel Requirements:** 25% or less

**Title 21 Band:** D

**Full Performance Band Level:** D

**Work Schedule:** Full Time

**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. Note: 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 Blood Review and Research (OBRR) plans and conducts research related to the development, manufacture, testing and activities of biological blood products, including those related to AIDS and those prepared by genetic engineering and synthetic procedures, in order to develop and maintain a scientific base for establishing standards designed to ensure the

continued safety, purity, potency and effectiveness of biological blood products.

The Division of Blood Components and Devices (DBCD) reviews, evaluates, and takes appropriate action on applications related to the manufacturing of blood and blood components, plasma expanders, blood collection and processing devices, blood storage solutions, and medical device applications related to immunohematology testing of blood and blood components intended for transfusion. DBCD maintains mission-related, scientific programs to evaluate factors affecting the safety and effectiveness of whole blood and blood components and develops related policies.

## Duties/Responsibilities

The incumbent serves as the Lead Clinical Laboratory Scientist of the Devices Review Branch (DRB) in the Division of Blood Components and Devices (DBCD) within the Office of Blood Review and Research (OBRR). This position reports to the DRB Branch Chief. The incumbent serves as the primary source of expertise within the team and act as a senior-level reviewer covering the entire lifecycle of the devices from pre-market and post-market, including review of analytical, clinical, and other data submitted in support of a variety of medical device and biologic programs. Programs encompass a variety of regulatory submissions that may include applications for biological license applications (BLAs), pre-market approval (PMAs), premarket notification of intent to market a product (510(k)s), Q-sub meeting requests, applications for investigational device exemptions (IDEs), De Novo, 513(g)s, Medical Device Reports (MDRs), Biological Product Deviation Reports (BPDRs), compliance with standards including performance standards, allegations, recalls, establishment inspection reports (EIRs), safety signals, and/or others.

Specifically, the Lead Clinical Laboratory Scientist will:

- Ensure Division and CBER-wide mission, vision, strategies, and goals are effectively communicated and integrated into the team's strategies, goals, objectives, and work.
- Coaches the team in the selection and application of appropriate problem-solving methods and techniques.
- Leads the team in identifying, distributing, and balancing workload among employees; arranging for team member training; monitors and reports on the status and progress of work.
- Conduct primary review of team members' memorandums drafted after the review of the medical device products.
- Conduct complex evaluation studies and reviews used to make recommendations permitting clinical medical technology in the US market, ensuring the safety and effectiveness of products and assess the manufacturer's quality and safety practices.
- Perform other duties assigned.

## 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.
- 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 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, Skills, and Education:**

- Relevant experience in applying concepts, principles, practices, and methodology of clinical laboratory technology especially blood typing assays and tissue typing assays; performing complex scientific data analysis related to the reviews of clinical laboratory tests; and providing reports of the scientific evaluation of clinical laboratory tests to summarize specific supporting reasons and specify any technical deficiencies.

## 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.

## 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 signed PMAP (if applicable), a copy of your unofficial transcripts (if applicable), and letter of interest with ***"Title 21 CBER/OBRR/DBCD/DRB Lead Clinical Laboratory Scientist***" in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **May 22, 2024**.

## Announcement Contact

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

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*FDA is an equal opportunity employer.*