**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 Vaccines Research and Review (OVRR)**
**Division of Review Management and Regulatory Review (DRMRR)**

**Application Period:** December 11, 2023 – December 20, 2023

**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:** Division Director

**Series:** 0401 (Biologist), 0601 (General Health Scientist), 0696 (Consumer Safety Officer), 1320 (Chemist)

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

**Salary:** Starting at $177,123 and is set commensurate with education and experience.

**Work Schedule:** Full Time

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

**Cures Band(s):** Band F

**Full Performance Band Level:** Band F

**Travel Requirements:** 25% or less

**Bargaining Unit:** 8888

**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 Vaccines Research and Review (OVRR) protects and enhances public health by assuring those available vaccines, allergenic extracts, and related product are safe and effective.

The Division of Review Management and Regulatory Review (DRMRR) is responsible for supporting administrative processing, review and coordination of Pre-Application submissions, Investigational New Drug Applications (INDs), amendments, Biologics License Applications (BLAs), and related supplements and submissions pertaining to vaccines, allergenic products, probiotics, test kits, and related products regulated by the OVRR. DRMRR coordinates the processing of INDs and BLAs through the other Divisions within the Office and coordinates licensing activities among the Divisions. DRMRR is also responsible for providing the regulated industry with advice on regulatory review processes and participating in the development of regulatory management procedures pertaining to the review of regulated biologics.

## Duties/Responsibilities

The incumbent serves as the Division Director of the Division of Review Management and Regulatory Review (DRMRR) within the Office of Vaccines Research and Review (OVRR) and manages daily operations of the Division. This position reports to the Director of OVRR. The incumbent is responsible for fully implementing the requirements of specific Equal Employment Opportunity, Food and Drug Administration (FDA), and Department of Health and Human Services (HHS) programs. Additionally, the incumbent carries out and supports other special HR programs of the Federal Government, HHS, and FDA as needed.

Specifically, the Division Director will:

- Provide oversight and leadership to the DRMRR staff and branch chiefs.
- Collaborate with OVRR Office Director to develop and execute the strategic plan for the growth of the staff and Office.
- Collaborate with the Branch Chief(s) to hire a diverse, qualified staff, and provides career coaching, growth, and personal development for direct/indirect reports.
- Oversee the administrative and regulatory screening of all Investigational New Drug applications (INDs), Investigational Device Exemptions (IDEs), Premarket Notifications (510(k)s), New Drug Applications (NDAs), Biologics License Applications (BLAs), and Premarket Approvals (PMAs) for products regulated by the Office.
- Direct the processing, management and reviews of marketing applications and supplements, review and concur on letters, monitor, and track regulatory actions, and ensure actions are consistent with applicable regulations, policies, and procedures related to IND/IDE, BLA/PMA/NDAs regulated by the Office.
- Oversee the review of INDs, IDEs, 510Ks, Humanitarian Device Exemptions (HDEs), and PMAs for products regulated in OVRR.
- Develop policies and procedures applicable for the evaluation of INDs/IDEs and BLA/PMA/NDA marketing applications regulated by the Office in the absence of Center-level policies and procedures.
- Participate in evaluating adequacy of the content of labeling for products regulated by the Office.
- Oversee and concur on written and oral communication from the Division.
- Provide technical advice and regulatory expertise to the Division staff and the Agency on products regulated in OVRR.
- Attend formal meetings between sponsors, applicants, manufacturers, and Office personnel.
- Ensure databases are maintained on IND/IDE and marketing application reviews activities.
- Provide input on collaborative research and management of contract-supported activities.

**Supervisory Responsibilities:**

**Organizational Management**: Manages a Division.
**Program Management**: Runs a program of singular discipline focus in the Center. Oversees or coordinates multiple functional activities.
**Resource Management**: Monitors and reports on resources needed to run a Division in the Center.
**Personnel Performance Management**: Counsels and rates immediate subordinates.
**Human Capital Management**: Identifies employee competency 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.
- 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 or below Education/Graduate Training Requirements 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/Graduate Training Requirements:**

*0401 Series (Biologist)*

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

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*0601 Series (General Health Scientist)*

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

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*0696 Series (Consumer Safety Officer)*

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical

sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

OR

Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

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*1320 Series (Chemist)*

Candidates must possess a bachelor's degree or higher in chemistry, biochemistry, or molecular/cellular biology. The degree must be from an accredited program or institution.

**Desired Education:**

- Candidates would ideally have a bachelors or higher degree in a scientific or medical discipline or other field (e.g., project management or administration) related to regulatory project management.

**Desired Professional Experience:**

- An experienced project manager with a strong scientific background
- Strong leadership and skill in strategic planning, problem solving, and making policy and programmatic decisions
- Knowledge and experience regarding FDA review policies
- Supervisory experience
- Skilled at building partnerships and collaborations with internal or external stakeholders

## 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 PMAP (if applicable), unofficial transcripts and letter of interest with ***"CURES CBER/OVRR/DRMRR Division Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **December 20, 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.*