U.S. FOOD & DRUG ADMINISTRATION

TITLE 21 CURES ANNOUNCEMENT

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)
OFFICE OF VACCINES REVIEW AND RESEARCH (OVRR)

Position: Director, Office of Vaccines Review and Research (OVRR)

Series: This is an interdisciplinary position that may be filled in the following series: Biologist (401), Microbiologist (0403), and Physician (0602).

Location(s): Silver Spring, Maryland

Area of Consideration: Open to the Public

Travel Requirements: 25% or less

Application Period: November 15, 2021 – January 15, 2022

Cures Band: G

Full Performance Band Level: G

Cures Position Type: Executive (Supervisory)

Salary:

- Microbiologist (0403), Biologist (401) = Table 1: Starting at $199,213 and is set to commensurate with education and experience.
- Physician (0602) = Table 3: Starting at $235,000 and is set to commensurate with education and experience.

Conditions of Employment: United States Citizenship or Nationals.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

Special Notes: This position is being filled under an excepted hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate/s selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of the authority.

Additional information on 21st Century Cures Act can be found here.

Introduction:
The Food and Drug Administration (FDA) 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 mission of the Center for Biologics Evaluation and Research (CBER) 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.

The Office of Vaccines Research and Review (OVRR) protects and enhances public health by assuring that available

vaccines, allergenic extracts, and related products are safe and effective.

Position Summary:
The Director reviews and evaluates the safety and efficacy of investigational new drug applications (INDs) and IND amendments for vaccines and related biological products, providing guidance and recommendations to IND sponsors with regard to the chemistry, manufacturing and control information, preclinical safety assessments and first-in-man clinical trials for these products. Regulatory actions include but are not limited to approval or disapproval of the proposed first-in-man clinical studies. Performs the investigational device exemption (IDE) review process for devices related to vaccines and related products regulated by the office.

The Director reviews and evaluates the safety and efficacy of biologic license applications and amendments submitted by manufacturers of preventive vaccines for infectious disease indications and related biological products, including labeling, and takes regulatory action accordingly. The Director plans and conducts research related to the development, manufacture, and testing of vaccines and related products, including those for pandemic influenza vaccines and those prepared by genetic engineering and synthetic procedures and all other emerging Infectious diseases, to support the regulatory process and to assist in establishing methodologies and standards to ensure the continued safety, purity, potency, and effectiveness of products regulated by this office.

Specifically, the Director, OVRR serves as the principal advisor to the Center Director on all matters pertaining to review and evaluation of vaccine-related biological Products, as well as, but not limited to:

- Develops guidance, policies and procedures governing the pre-market approval review and evaluation of vaccines and related products in keeping with the provisions of the Public Health Service Act and applicable provisions of the Federal Food Drug and Cosmetic Act.
- Evaluates clinical experience and reports of adverse events as necessary, implements new authorities granted by the Food and Drug Administration Amendment Act Title IX, Section 901 to require, as appropriate, post marketing studies and clinical trials, safety labeling changes, and risk evaluation and mitigation strategies for vaccines and related biological products to ensure product safety throughout their life cycle, in collaboration with the Office of Biostatistics and Epidemiology.
- Develops and refines pathways for regulatory evaluation of novel vaccines prepared by genetic engineering and synthetic procedures, antigen specific immunomodulators, allergenic products, and diagnostic antigens. Cooperates with other Center components, as appropriate, tests vaccine and related products submitted for release by manufacturers.

Duties/Responsibilities:
The Director reviews and evaluates the safety and efficacy of biologic license applications and amendments submitted by manufacturers of preventive vaccines for infectious disease indications and related biological products, including labeling, and takes regulatory action accordingly.

The Director serves as a key contributor to the worldwide efforts on yearly seasonal influenza vaccine strain selection as part of the World Health Organization (WHO) Reference Laboratories network, as well as to the worldwide efforts to generate appropriate reference virus strains and reference reagents for influenza vaccine production, both seasonal and pandemic. Plans and conducts research to provide the requisite scientific database for the establishment and use of reference preparations.

The Director plans and conducts research related to manufacture, pre-market evaluation of safety, purity, and efficacy of vaccines and related products to support regulatory process and develop scientific base for establishing standards to maintain high quality of products regulated by this office. Works on reduction, refinement, and

replacement of animal tests used to ensure safety and potency of vaccines and related products (3R concept). Performs research to advance new concepts of rational design of vaccines against emerging and re-emerging diseases including pandemic Influenza and agents of bioterrorism.

The Director initiates, coordinates, and/or responds to requests for information of interest with Agency cooperation on vaccine-related matters. Within the context of established Agency policy, advises the Center Director on a specific course of action. Serves as the approval authority, unless delegated for INDs and PLAs related to vaccines, allergens, and antigen specific immunoregulators. This includes amendments and supplements to the referenced applications.

Supervisory Responsibilities:

Organizational Management: Manages an Office.

Program Management: Runs a multi-disciplinary program in the Center. May run two or more smaller, multi-disciplinary programs in the Center. Identifies specific activities needed to achieve desired outcomes. Organizational staffing patterns are primarily homogeneous, but may also have staff in various scientific, professional, technical, or administrative occupational series.

Resource Management: Monitors and reports on resources needed to run an Office or a multi-disciplinary program in the Center.

Personnel Performance Management: Counsels and rates immediate subordinates.

Human Capital Management: Identifies employee competencies necessary to meet organizational capabilities goals.

Professional Experience/Desirable Qualifications:

- Primary responsibility for managing a scientific research office.
- Developing short- and long-term programmatic goals.
- Communicating scientific concepts to a lay audience.
- Supervisory experience is highly desirable.

Desirable Education:

- Candidates would ideally have a master's degree, doctoral degree, or both in Biology or Microbiology, or a medical degree.

Basic Qualifications:

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

Conditions of Employment:

- One-year probationary period may be required.
- Background and/or Security investigation required.
- U.S. citizenship is required.
- 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.
- This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office

website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Application Procedures:

Submit electronic resume or curriculum vitae, SF50, and letter of interest with ***"CURES CBER/OVRR Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **January 15, 2022.**

Equal Employment Opportunity Policy

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 Policy

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.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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