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 Compliance and Biologics Quality (OCBQ)

Application Period: January 26 – February 16, 2023

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: Associate Director for Manufacturing Quality

Series: 301

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

Salary: Starting at $155,700

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 is the federal agency responsible for protecting the public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by helping to ensure the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

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 public health through the regulation of biological and related products including blood, vaccines, allergenics, human tissues, and cellular and gene therapies. CBER protects and advances the public health by helping to ensure that biological products are safe, pure, and potent. CBER also provides the public with information to promote the safe and appropriate use of biological products.

OCBQ's mission is to ensure the quality of products regulated by CBER over their entire lifecycle through pre-market review and inspection, and post-market review, surveillance, inspection, outreach and compliance.

Duties/Responsibilities

The incumbent serves as an Associate Director for Manufacturing Quality within the Office of Compliance and Biologics Quality (OCBQ). As Associate Director, the incumbent serves as a senior advisor to the Office Director and Deputy Office Director, OCBQ, concerning the manufacturing of CBER-regulated biological products, including advising on issues involving compliance with current good manufacturing practice requirements, other regulatory compliance issues, enforcement, and policy issues related to manufacturing, in close consultation with the Associate Director for Policy, OCBQ. The Associate Director assists in developing and evaluating potential impacts of recommended policies that affect CBER compliance and enforcement, and advises on regulatory compliance, enforcement, and policy work involving other federal and state regulatory counterparts. The incumbent serves as an expert technical resource and leading authority on the planning and management of projects that have a significant impact on the Agency's operations and programs, provides guidance on the most challenging problems facing the Agency having responsibility for a program of national or international scope and impact, and develops strategies for planning and/or implementing major Agency programs.

Specifically, the Associate Director will:

- Prepare, review, and/or approve final drafts of compliance, enforcement, related policy documents, and communications strategies and materials for clearance, as appropriate, by the Office Director, Deputy Office Director, Associate Director for Policy, and Center senior officials and, as necessary, the CBER Center Director, other FDA Centers and the Office of Regulatory Affairs (ORA), the Office of the Chief Counsel, and the Office of the Commissioner.
- Plan, develop, and direct compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, purity, and potency of biological products.
- Strategically implement programs and projects to identify, assess, and prioritize the public health significance and patient risk associated with product quality and safety concerns presented throughout the product lifecycle.
- Lead the development of enforcement and compliance policy standards and actions and ensure uniform interpretation.
- Provide expert advice and guidance on government programs and policies which are of significant interest to the public and Congress, e.g., the programs cut across or strongly influence a number of agencies, and/or the employee's recommendations directly
- Accomplish key governmental functions and substantially redirect federal efforts or policies related to major national issues.
- Research regulatory issues, utilize resources and examine relevant facts to develop a compliance or enforcement action, and present findings and make appropriate recommendations for action to the Office Director, Deputy Office Director, and senior managers and other high level officials.
- Independently develop policies and programs involving complex and high priority matters affecting the regulation of biological products, and draft or critically review embodying policy and program proposals and decisions, including regulations, proposed legislation, and policy statements.
- Use resources such as the US Code, the Code of Federal Regulations, the Federal Register, and others, to conduct legal research regarding established precedents in order to develop and support legally sufficient regulations, and policies.
- Lead working groups of scientific, regulatory and legal experts within CBER and across the Agency to develop new or revised regulations and drafts the resulting notices of proposed rulemaking.

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.

- 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: OPM Occupational Series Qualification Requirements

Desired Education: Candidates would ideally have a graduate degree or higher (*i.e.*, Masters, J.D., Ph.D., and/or M.D.).

Desired Professional Experience: Candidates would ideally possess:

- Demonstrated understanding and application of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and implementing regulations.
- In-depth knowledge of the current good manufacturing practice requirements for drugs.
- Experience handling and/or overseeing FDA compliance and/or enforcement actions.
- Superior verbal and written communication skills.
- Ability to actively and skillfully question and test previously held assumptions; recognize ambiguity; make informed judgments; and justify, prioritize, and make critical decisions.
- Experience working collaboratively with a diverse cadre of customers and stakeholders.
- High-level organizational skills.

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), copies of transcripts (if applicable), and letter of interest with ***"CURES CBER/OCBQ Associate Director for Manufacturing Quality"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **February 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.