Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Clinical Policy and Programs (OCPP)
Office of Combination Products (OCP)

Application Period: November 15 – December 2, 2022

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: Office Director, Office of Combinaton Products (OCP)

Series: 301 (Regulatory Counsel), 401 (Biologist), 403 (Microbiologist), 601 Health Scientist), 602 (Physician), 660 (Pharmacist), 800 (Engineer)

Location(s): Remote

Salary: Starting at $168,914-$310,000

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: n/a

Bargaining Unit: 8888 (Non Bargaining Unit)

Relocation Expenses Reimbursement: Not applicable

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 mission of the Office of Clinical Policy and Programs (OCPP) is to advance the public health by developing, leading, and executing programs and cross-cutting initiatives that support FDA's centers in making effective, safe, and innovative medical products available to the American people. OCPP also coordinates and supports patient engagement activities across the medical product centers to foster awareness and collaboration with patients, caregivers, their advocates, and the FDA.

The FDA Office of Combination Products (OCP) was established on Dec. 24, 2002, as required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The law gives the Office broad responsibilities covering the regulatory life cycle of drug-device, drug-biologic, and device-biologic combination products. Congress gave OCP specific programmatic, regulatory responsibilities to ensure the prompt, consistent and appropriate assignment, premarket review and postmarket regulation of combination products. OCP's responsibilities cover the regulatory life cycle of combination products, and include decision making authority for product jurisdiction decisions and the oversight of specific premarket and postmarket processes.

Duties/Responsibilities

Director of OCP serves as an advisor to the OCPP Office Director, FDA's Chief Medical Officer, and other key Agency officials on legislation, regulations, programs and policies concerning the regulation of combination products. The incumbent plans, develops, coordinates and administers Agency programs and activities required to implement specific provisions of MDUFMA related to OCP. As such, the incumbent will be responsible for handling the unique challenges that OCP continually faces from external stakeholders, Congressional oversight, intercenter process evolution posed by PDUFA and MDUFMA, and the nuances of increasingly novel drug-device-biologic technologies. Among the incumbent's many responsibilities will be representing the FDA, and participating as the Agency's regulatory authority on all matters related to the regulation of combination products in conferences, meetings and discussions with top level Agency and Departmental officials, regulated industry representatives, and the medical, scientific and health-related professional organizations.

The OCP Director is responsible for the assignment of the Center with primary jurisdiction for combination products, as well as developing jurisdictional programs and formulating jurisdictional policies for combination products. The incumbent will review and update agreements, guidances or practices specific to the assignment of combination products. The incumbent will serve as the Agency focal point and primary contact for the regulation of combination products and provides expert and authoritative advice, guidance, assistance, interpretations, consultations and recommendations to top level and senior Agency and Departmental officials.

The OCP Director will serve as the Agency advocate for combination products to ensure that appropriate attention is paid to, and resources invested in, the premarket review and postmarket regulation of combination products, as well as prepare annual reports to Congress

on the activities and impact of the Office.

Supervisory Responsibilities:
Organizational Management: Manages an Office – maintaining and establishing decision making framework across the organization.
Program Management: Runs a multi-disciplined program in the Office. Oversees or coordinates multiple functional activities.
Resource Management: Monitors and reports on resources needed to run an Office.
Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Identifies employee competency gaps.

EEO responsibilities:
The incumbent is responsible for furthering the goals of equal employment opportunity (EEO) by taking positive steps to assure the accomplishment of affirmative action objectives and by adhering to non-discriminatory employee practices in regard to 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. Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Center in the following: (1) merit promotion of employees and recruitment and hiring; (2) fair treatment of all employees; (3) encouragement and recognition of employees' achievements; (4) career development of employees; and (5) full utilization of their skills.

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:

Regulatory Counsel, 301 Series: There are no Individual Occupational Requirements for this series. For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Education: Degree: A juris doctorate degree from an accredited institution of higher learning.

Biologist, 401 Requirements: Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.
Or
Combination of education and experience: Courses equivalent to a major, plus appropriate experience or additional education.

Microbiologist, 403 Requirements: Degree: microbiology; or biology, chemistry, or basic medical science that included at least 20 semester hours in microbiology and other subjects related to the study of microorganisms, and 20 semester hours in the physical and mathematical sciences combining course work in organic chemistry or biochemistry, physics, and college algebra, or their equivalent.
Or
Combination of education and experience: courses equivalent to a major in microbiology, biology, chemistry, or basic medical science that included courses as shown in A above, plus appropriate experience or additional education.

Requirements for 601 series: Bachelor's/Graduate/higher level degree: major study in an academic field related to 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.

Desired Education: Ideal candidate will possess Ph.D. in related science

Physician, 602 Requirements: One-year probationary period may be required; Official transcripts required; Degree must have been accredited by the Council on Medical Education of the American Medical Association; Association of American Medical Colleges; Liaison Committee on Medical Education; Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained.

Pharmacist, 660 Requirements: A doctoral degree in Pharmacy that is recognized by the Accreditation Council for Pharmacy Education (ACPE) or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained. Applicants must be licensed to practice pharmacy in a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

Engineering, 800 Requirements: This group includes all classes of positions the duties of which are to advise on, administer, supervise, or perform professional, scientific, or technical work concerned with engineering or architectural projects, facilities, structures, systems, processes, equipment, devices, material or methods. Positions in this group require knowledge of the science or art, or both, by which materials, natural resources, and powers are made useful.

Professional Experience:

- An experienced scientist also highly skilled at applying all aspects of operations management. May be proficient at one or more aspects of other occupational specialties.

- Strong leadership and skill in leading/directing large organizations, including strategic planning and problem solving, making policy and programmatic decisions and overseeing office management, i.e., hiring, professional development, IT development, contracts management, budget, records management, etc.

Desired Professional Experience:
• In-depth knowledge of the Agency's policies, and scientific and regulatory requirements and review programs as they relate to medical products
• Strong background in science and office operations
• Talent for building partnerships and collaborations with public and private 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 Requirement: 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

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

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.

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

How to Apply: Submit resume or curriculum vitae with cover letter by December 2nd to: Jessica Bennett. Candidate resumes may be shared with hiring official within OCPP with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions please contact Jessica Bennett at (Jessica.Bennett@fda.hhs.gov or 301-796-3070). Please reference Job Reference ID: OCP Deputy

Announcement Contact

For questions regarding this Cures position, please contact Jessica Bennett

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