**Title 21 Vacancy Announcement**
**Department of Health and Human Services (HHS)**
**Food and Drug Administration (FDA)**
**Office of Regulatory Affairs (ORA)**
**Office of Regulatory Management Operations (ORMO)**

**Application Period:** January 17, 2023 – February 7, 2023

**Area of Consideration:** 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:** Deputy Director, Office of Regulatory Management Operations

**Series:** AD-0341

**Location(s):** Rockville, MD

**Salary:** Starting at $177,123

**Work Schedule:** Full Time

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

**Full Performance Band Level:** Band F

**Travel Requirements:** 25%

**Bargaining Unit:** This is a non-bargaining unit position

**Hiring Incentives:** You may qualify for relocation and recruitment incentives, PCS, and Credible Service for Annual Leave in accordance with FDA 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 (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 that all such products marketed in the United States are adequately, truthfully, and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA's programs are global in scope and effect, and the agency's activities have a direct and significant impact on multibillion 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.

FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency regulatory activities. Over 5,100 ORA employees strategically located in district offices, resident posts, and laboratories throughout the United States perform inspections and investigations (including criminal investigations), wharf exams, sample collections and analyses, and carry out enforcement activities, education, and outreach directly to consumers, industry representatives, importers, and shippers as well as other stakeholders across the globe. ORA also works with its federal, state, local, tribal, territorial, and foreign counterparts to further the agency's mission. ORA is led by the Associate Commissioner for Regulatory Affairs (ACRA).

To view our ORA Vision, Mission, and Values please visit:
https://www.fda.gov/aboutfda/officeregulatory-affairs/ora-vision-mission-and-values

## Duties/Responsibilities

The incumbent serves as the Deputy Director, Office of Regulatory Management Operations (DD-ORMO). The DD-ORMO, along with the Assistant Commissioner for Regulatory Management Operations (ACRMO), has ORA-wide authority for strengthening the management of business programs and regulatory operations. Along with the ACRMO, the DD-ORMO oversees the Office of Training and Education Development (OTED), the Office of Workforce Management (OWM), and the Office of Budget, Facilities and Travel Support (OBFTS). In collaboration with the ACRMO, the DD-ORMO directs a staff consisting of a wide range of management, administrative, training, and technical disciplines with employees ranging from grade level through the executive level. Together, the Office of Regulatory Management Operations (ORMO) supports over 5,100 ORA staff and oversees a budget of approximately $1.3 billion. Additional responsibilities include:

- Serving, in collaboration with the ACRMO, as the principal source of expertise and advice to the ACRA on improving processes and introducing new technologies on an enterprise-wide basis. Provides direction and assists the ACRA in formulating, developing, and shaping the FDA Field's (both domestic and foreign) short- and long-range management and service improvement needs.
- The incumbent is responsible for ensuring the training and development investments focus on accessible, user-friendly design and promote business efficiencies. Furthermore, they are responsible for the alignment of administrative systems and policies with anticipated workforce needs to support comprehensive capacity building and consistent quality improvement programs.
- The DD-ORMO is responsible for overseeing a complex array of budget activities that includes updating facilities and new laboratory construction as well as the coordination of information system and technology management activities across

ORA.

- The DD-ORMO oversees the implementation of ORA business policies and procedures, including providing overall organization management direction to improve ORA integration and performance, developing measures, and achieving specific performance goals in ORA initiatives.
- The DD-ORMO ensures efficient, effective, and consistent administrative operations, resolves major challenges, and matters of key policy; promotes and leads major reviews and discussions regarding improvements in administrative/management operations and processes through regular and special meetings.
- Coordinates and integrates the efforts of scientific, professional, and other personnel across organizational lines to provide optimum use of manpower; and ensures that operational practices, approaches, methods, and techniques are the latest and most effective.
- In collaboration with the ACRMO, the incumbent provides authoritative advice, guidance, assistance, interpretations and recommendations to the ACRA and top-level ORA officials, program directors, scientific and professional personnel, departmental representatives, intra-governmental and international counterparts and others in such areas as: the need to develop new policies; questions, critical problems and controversial issues affecting ORA programs and activities; legislative proposals, congressional testimony and materials related to implementing, amending or modifying FDA laws and regulations; and integration of ORA programs to implement new or modified legislative and statutory authorities and program responsibilities.

**Supervisory Responsibilities:**

- Participates with the ACRMO and ACRA in the planning and management of the ORA's regulatory operational activities, providing authoritative judgments and recommendations. In conjunction with the ACRMO and ACRA, the incumbent provides guidance for unprecedented policy matters or issues involving large expenditures of resources.
- Directs the delegation of authority to subordinate supervisors and monitors their performance in accomplishing the assigned workload.
- Leads in a proactive, customer-responsive manner consistent with ORA's vision and values, effectively communicating program issues to both internal and external audiences. Ensures financial and managerial accountability by acting with prudence when executing fiduciary responsibilities. Demonstrates high integrity and adheres to the highest ethical standards of public service. Uses effective business practices including balanced measures of results, values, and invests in each employee; emphasizes empowerment and two-way communication.
- Exercises leadership to ensure that all programs under their direction reflect the principles of workforce diversity in areas such as recruitment and staffing, employee development, staff assignments, and communications.

**Organizational Management**: Assists in managing a Super Office.

**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.
- 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.*

**Professional Experience:**

- Full working knowledge of regulatory management operations.
- Knowledge of principles, theories and practices that enable the incumbent to carry out tasks related to regulatory management operations.
- Demonstrated experience in making managerial and technical decisions required for successful program execution, administration, and management.
- Demonstrated experience managing and directing employees engaged in management operations, and training.
- Experience in budget formulation and staff development.

## 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: If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

## 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

Applications will be accepted from all qualified internal and external applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position, detailed resume and bibliography, SF-50 for current federal employees only, transcript (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee, oraexecutiveandscientificrecruitment@fda.hhs.gov. Applications will be accepted through February 7, 2023. Please reference Job Reference ID: Deputy Director, ORMO.

## Announcement Contact

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

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*FDA is an equal opportunity employer.*