



Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Medical Products and Tobacco Operations (OMPTO)

Application Period: March 16, 2023 – April 13, 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: Associate Director of Advanced Medical Products Manufacturing

Series: [AD-0696](#)

Location(s): ORA Headquarters, and district offices in Atlanta, Baltimore, Chicago, Cincinnati, Dallas, Denver, Detroit, Florida, Kansas City, Los Angeles, Minneapolis, New England, New Jersey, New Orleans, New York, Philadelphia, San Francisco, San Juan, Seattle

Salary: Starting at \$177,123

Work Schedule: Full time

Cures Band(s): Band F, Table 1

Full Performance Band Level: Band F

Travel Requirements: Up to 50%

Bargaining Unit: 8888

Hiring Incentives: 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 4 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives may include recruitment or relocation incentives in accordance with FDA, Title 21 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 animal, tobacco, and radiation emitting devices are 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 national 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.

To view our ORA Vision, Mission, and Values please visit:

<https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values>

FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency regulatory activities. Over 5,000 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 nation. 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).

The Office of Medical Products and Tobacco Operations (OMPTO) has responsibility for inspections, investigations, compliance and enforcement of medical products and tobacco facilities regulated by the FDA. The incumbent is expected to have knowledge of inspections of regulated products and manufacturers, provides expert advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Agency leaders on inspectional and compliance operations and emergency response activities related to advanced manufacturing and medical countermeasure regulated products.

The Associate Director for Advanced Medical Product Manufacturing (AD-AMPM) serves as the ORA authority with the advanced medical product manufacturing industry and FDA authority on medical product programs.

The AD-AMPM reports directly to the Deputy for Therapeutics Quality and Emerging Regulatory Operations.

Duties/Responsibilities

Participates in and advises on domestic and foreign inspections and investigations related to the most complex, controversial, and precedent setting scientific and regulatory problems involving industry practices and products within drugs, biologics and medical devices and

radiological health.

Meets with industry representatives to exchange information and provide advice and guidance regarding major problems/deficiencies encountered during inspections; review reports with emphasis on appropriate alternatives to meet program objectives.

Serves as a subject matter expert in inspectional and investigational techniques, providing authoritative advice and counsel within and outside ORA in advanced manufacturing for medical products involving current and emerging technologies for the production, testing, and control of non-sterile and sterile medical products, engineering principles and practices, and current good manufacturing practices related to medical products.

Resolves a broad range of issues concerning implementing legislation, regulations, policies and/or procedures affecting pharmaceutical, biologics and medical devices and radiological health programs. Makes recommendations that often serve as the basis for new systems, legislation, regulations, and/or programs.

Participates in interagency meetings or conferences as an authority on external and internal cross-Agency pharmaceutical, biologics and medical device and radiological health program committees, workgroups, and task forces. Represents the office in departmental meetings and conferences.

Supervisory Responsibilities: Leads a team of skilled senior CSOs in medical counter measures and advanced manufacturing operations. Advises on needed training and development, to ensure Investigators are staying current with trends for novel medical countermeasures and products.

Projects are often self-initiated, based on current events, the incumbent's expertise, and determination of what needs to be done. Although the incumbent consults with the DD-OMPTO, s/he exercises considerable autonomy in identifying issues or projects to manage, carrying out the work, either individually or through a team effort which s/he leads, resolving all issues, coordinating with stakeholders, providing authoritative advice on complex issues that cut across multiple organizational elements, and initiating new projects or activities as needed, including assessing the need for additional resources to accomplish proposed projects. The supervisor is kept informed of assignment status and any potentially noteworthy situations or developments with broader policy implications are discussed before a final course of action is determined.

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.
- This position requires the incumbent have the following: current Driver's License.
- This position requires up to 50% travel.

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: The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, [U.S. Department of Education](#) at the time the degree was obtained. For more information please see the link to: [OPM Occupational Series Qualification Requirements for:](#)

[Consumer Safety Series, 0696](#)

Professional Experience:

- Principles, theories, and practices related to advanced manufacturing.
- Knowledge of the FD&C Act and regulations, related acts, laws legislation and precedents, that govern the procedures and guidance materials of ORA and associated organizations.
- Knowledge of inspectional and investigative techniques associated with the regulation of the domestic and international industries within the medical products and advanced manufacturing technologies functional program area.
- Knowledge of the principles and practices of manufacturing technologies in medical products.
- Knowledge of legislation, laws, precedents, and regulations which govern ORA's activities related to Medical Products.
- Skill in oral and written communications to make clear, convincing presentations; represent the Agency at meetings and conferences; interact with high level officials and representatives from public and private public health organizations.

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

This position requires a Secret security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of sensitive, secret information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

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 based on 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

Application will be accepted from all qualified internal and external applicants. Applicants must submit a letter of interest addressing experience in the major duties and responsibilities of the position, a detailed current résumé, redacted SF-50 (for federal employees only), and transcripts (with foreign credentials evaluation if applicable) to the ORA Executive Recruitment Team at: ORAExecutiveandScientificRecruitment@fda.hhs.gov. Applications will be accepted through April 13, 2023. Please reference Associate Director, AMPM in the subject line.

Announcement Contact

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

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