Title 21 Detail 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: February 3, 2023, to February 10, 2023

Area of Consideration: Open to current FDA employees only. Must be currently employed by the Food & Drug Administration, serving on an appointment in the excepted or competitive service.

Position: Associate Director of Advanced Medical Products Manufacturing

Series: 0696

This announcement is for a 120-day detail.

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

Work Schedule: Full Time

Title-21 Band: Band F, Table 1

Salary: Starting at $177,123

Travel Requirements: Up to 50%

Bargaining Unit: 8888

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. Medical Product and Tobacco Centers inspects 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; reviews 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 the area of 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.
- 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 to have the following: current Driver's License.
- This position requires up to 50% travel.

Qualifications

To be placed into a Title-21 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 Title-21 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 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.

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.

How to Apply

Applicants must submit a current résumé, a current SF-50 redacted for complete SS# and birth year (for federal employees only), proof of degree or transcripts (with foreign credentials evaluation if applicable), and a brief (one-page or less) statement explaining your interest and qualifications for this position to the ORA Executive Recruitment Team at: ORAExecutiveandScientificDetails@fda.hhs.gov. Applications will be accepted through February 10, 2023. Please reference Associate Director, AMPM in the subject line.

Announcement Contact

For questions regarding this Title-21 position, please contact ORAExecutiveandScientificDetails@fda.hhs.gov.

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

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