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 25 to April 09, 2021

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: Supervisory Consumer Safety Officer (Advanced Medical Products Manufacturing)

Series: 0696, Consumer Safety

Location(s): Silver Spring, MD

Work Schedule: Full time

Salary: Starting at $163,962

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: Up to 50%

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 (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.

Join FDA and serve on the frontlines protecting our nation's public health safety within the Office of Regulatory Affairs (ORA). At ORA, we work in a range of program areas and locations, with 227 offices and 13 laboratories throughout the nation or around the world. Our employees inspect product facilities; investigate criminal violations; analyze lab samples; provide administrative services, and much more. Be a part of ensuring that the thousands of products we use every day are safe and effective.

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

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

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 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 Supervisory Consumer Safety Officer for Advanced Medical Product Manufacturing (SCSO-AMPM) serves as the ORA authority with the advanced medical product manufacturing industry and FDA authority on medical product programs.

The SCSO-AMPM repots directly to the Deputy Director, Office of Medical Products and Tobacco Operations.

Duties/Responsibilities

Develops Agency policy, guidance and/or standards relating to domestic and international program area issues; develops new programs and initiatives that affect domestic and foreign industries and ensures staff training for inspections and compliance of advanced manufacturing.

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 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. Provides technical consultation to enforcement officials, general counsel, ORA and center leadership, and state officials.

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

Leads the development and presentation of national/international training programs and materials for advanced manufacturing including areas of pharmacueticals, biologics and medical devices and radiological health programs. Participates in course advisory groups and / or curriculum committees and acts as a training instructor. Acts as a liaison with industry groups and professional organizations to evaluate and leverage training expertise from outside of FDA.

Maintains contacts with other industry, federal, state, local and foreign regulatory agencies, trade and cooperative organizations, FDA Centers corresponding to the advanced manufacturing specialty area(s) and industry in an effort to achieve and maintain a well informed and trained investigative workforce on advanced manufacturing and the uniform approach to the resolution of problems in the domestic, import and foreign industries and venues.

Participates in interagency meetings or conferences as an authority on external and internal cross-Agency medical device and radiological health program committees, workgroups and task forces. Represents the office in departmental meetings and conferences. Advocates FDA/ORA views and programmatic positions.

Supervisory Responsibilities: Leads a team of skilled senior investigators 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.
- 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: Consumer Safety Series, 0696

Desired Education: Our ideal candidate will possess Bachelor or graduate/higher level degree

with major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position, including one of the following: biological sciences, chemistry, pharmacy, physical sciences, medical science, engineering, veterinary consumer laws, chemistry, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provide knowledge directly related to consumer safety officer work in advanced medical product manufacturing.

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.

Desired Professional Experience:

Mastery of:

- Principles, theories and practices related to advanced manufacturing.
- Comprehensive 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.
- 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.
- Thorough knowledge of the principles and practices of manufacturing technologies in medical products.
- Legislation, laws, precedents, and regulations which govern ORA's activities related to Medical Products.
- Skill with independent inspections that have resulted significant public health outcome.
- 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

Background Investigation/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 highly sensitive 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 is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at 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: 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: ORA Executive Recruitment.

Announcement Contact

For questions regarding this Cures position, please contact Kathleen Davis.

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

FDA is an equal opportunity employer.