Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Pharmaceutical Quality (OPQ)
Office of Quality Surveillance (OQS)

Application Period: July 26, 2022 – August 9, 2022

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.

Commissioned Corp Officers are eligible to be considered.

Position: Consumer Safety Officer
Series: AD-0696

Location(s): Silver Spring, MD

Work Schedule: Full Time

Salary: Starting at:
Band A - $74,950
Band B - $89,834
Band C - $106,823

Cures Band(s): Band A/B/C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

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) 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 Center for Drug Evaluation and Research (CDER) is responsible for regulating prescription...
drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs (OTC). CDER’s drug regulatory responsibilities include premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotion activities; review, monitoring, and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

The Office of Pharmaceutical Quality (OPQ) oversees and coordinates the overall regulation of human pharmaceutical quality within CDER, including submission review, manufacturing facility assessment, and surveillance of the quality of marketed pharmaceutical products.

The Office of Quality Surveillance (OQS) is OPQ’s focal point to assure that quality medicines are available through signal detection, data analysis, review of the state of quality, and proactive stakeholder engagement.

Duties/Responsibilities

As a Consumer Safety Officer (CSO), the incumbent provides authoritative guidance and consultation regarding current good manufacturing practices (CGMPs) for pharmaceutical manufacturing in the context of on-site inspections; and, supports the human drug surveillance program through qualitative and quantitative regulatory assessments of quality metrics, quality management maturity, pharmaceutical quality system effectiveness, and other related quality intelligence available throughout the product lifecycle to engage business partners about resource allocation, work planning, enforcement discretion, inspectional strategies, and regulatory policy needs and stakeholders about the state of pharmaceutical quality and future quality surveillance program development.

Band A
Under close supervision, the incumbent:

- Prepares requests for site quality record, from pharmaceutical manufacturing sites.
- Participates in the evaluation of records from pharmaceutical manufacturing sites.
- Assists with conducting post-market quality-based assessments of sites and products.
- Participates in inspections as necessary.

Band B
Under moderate supervision, the incumbent:

- Meets duties and responsibilities outlined in Band A above.
- Conducts post-market quality-based assessments of sites and products.
- Conducts research into regulatory precedents and legislative history of the Acts enforced by FDA and prepares briefings for top FDA managers based on such research.
- Advises industry, consumers, and Agency officials on the interpretation, intent, and impact of programs and policies, scientific findings, and decisions.
- Participates in inspections as necessary.
**Band C**

- Meets duties and responsibilities outlined in Band B above.
- Serves as the coordinator for program requests for site quality records from pharmaceutical manufacturing sites.
- Independently evaluates records and site inspection reports from pharmaceutical manufacturing sites.
- Leads or participates in inspections as necessary.
- Informs the strategic development and execution of the Drug Quality Sampling and Testing program.
- Manages and coordinates special projects and office-wide initiatives as assigned by the supervisor.

Supervisory Responsibilities: n/a

**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 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.

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 Officer, AD-0696 Series**
Degree: A bachelor’s or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

OR

Combination of education and experience—courses consisting of at least 30 semester hours in the fields of study described above, plus appropriate experience or additional education.

For more information, please see: OPM Occupational Series Qualification Requirements.

**Desired Professional Experience:**
Our ideal candidate will possess:

- Ability to identify and analyze problems; weigh the relevance and accuracy of information; generate alternative solutions; and make recommendations.
- Ability to communicate and work with staff across the organization and with differing expertise; demonstrated ability to collaborate across boundaries to work toward common goals.
- Ability to work as a contributing and collaborative team member.
- Ability to organize time effectively and move work forward.

**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: Non-Sensitive/Moderate Risk

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 the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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 webpage: 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

All qualified candidates should submit their resume with cover letter and unofficial transcripts (if you have foreign transcripts, please submit foreign transcript evaluation from an accredited company) by August 9, 2022, to: OPQOQSRecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring officials within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions, please contact OPQOQSRecruitment@fda.hhs.gov.
How I Will Be Evaluated
Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact
For questions regarding this Cures position, please contact Dominique.Mitchell@fda.hhs.gov.

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

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