TITLE 21 VACANCY ANNOUNCEMENT

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 Policy for Pharmaceutical Quality (OPPQ)
Immediate Office (IO)

Position: Lead Regulatory Counsel

Series: AD – 301

Location(s): Silver Spring, MD

Travel Requirements: 25% or less

Application Period: December 17, 2020 – January 15, 2021

Salary: Starting at $142,701 (Cures Band E)

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: Relocation expenses will not be paid.

Special Notes:

This position is being filled under an excepted 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 compensated under the provisions of the authority. Additional information on 21st Century Cures Act can be found here.

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 are 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 Policy for Pharmaceutical Quality (OPPQ) is responsible for developing and clearly communicating science and risk-based policies and standards related to drug product quality, including application review and inspection. OPPQ will examine current policies, establish new policies, and identify research needs to ensure that drug quality policies support the availability of quality medicines for all Americans.

Position Summary:

As **Lead Regulatory Counsel,** the incumbent assumes primary responsibility for ensuring that regulations and policies developed in the assigned area are consistent with statutory requirements and existing policy; that their need is justified, and that scientific and regulatory decisions have been appropriately documented.

Duties/Responsibilities:

- Provides regulatory support for OPPQ and OPQ senior leadership and Office-led project working groups in the development and revision of policies, programs, regulations, and guidance involving the most complex and highest priority matters affecting drug quality
- Serves as an expert consultant in regulatory matters related to quality and is frequently called on to advise others concerning FDA statues and regulations related to quality
- Reviews policy and other regulatory documents drafted by other center offices that impact pharmaceutical quality regulation. Evaluates other office policies (regulations, guidance, and programs) as to impact on drug quality regulation and provides recommendations to harmonize
- Performs policy/regulatory reviews of the most complex or controversial quality-related petitions and critically assesses policy/regulatory reviews performed by other staff, including regulatory counsels, on petitions that raise issues that have an industry-wide effect, as well as those that pertain to the marketing status of individual products
- Provides advice and assessments of the impact of actual and proposed Administration or Congressional actions on the programs, functions, and activities of OPQ, and leads

OPQ in the drafting of technical assistance on proposed legislation related to pharmaceutical quality issues

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. Click here for more information on Equal Employment Opportunity (EEO) for federal employees & job applicants

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.

Professional Experience/Desirable Qualifications AD-301:

To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, and abilities, and competencies necessary to perform at the level of the position. Qualifying experience involves knowledge of federal regulatory programs and possession of a Juris Doctor degree from an accredited institution of higher learning. The education must have been obtained at a college, university, or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

- Knowledge of drug law and experience leading other employees
- Possession of significant knowledge of regulatory practice, policies, and procedures, with experience related to the regulation of pharmaceutical quality is desired
- Demonstrated ability to identify and analyze problems; weigh the relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations
- Expert ability to communicate and work with staff at all levels of the organization and varying levels of domain expertise; demonstrated ability to collaborate across boundaries to build strategic relationships and achieve common goals
- Ability to work independently and as a contributing, collaborative team member
- Ability to organize time effectively, determine priorities, and move work forward

Conditions of Employment:

1. **Security Clearance:**

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 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.

2. **Ethics 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.

3 . How to Apply:

All qualified candidates should submit a curriculum vitae and cover letter describing why you are uniquely qualified for this position and unofficial transcripts (if you have foreign transcripts please submit foreign transcript evaluation from an accredited company), electronically by **January 15, 2021** to: OPQ_Cures_Recruitment@fda.hhs.gov. Candidate resumes may be shared with the hiring official in CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share." For questions please contact Dominique Mitchell, Supervisory Administrative Officer, via email at Dominique.Mitchell@fda.hhs.gov. Please reference Job Code: **Lead Regulatory Council, OPPQ.**

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

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