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 Generic Drugs (OGD)
Office of Bioequivalence (OB)
Division of Bioequivalence I (DBI), Division of Bioequivalence II (DBII),
Division of Bioequivalence III (DBIII)

Application Period: April 18, 2023 – May 1, 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.

*Multiple vacancies.

Position: Pharmacokineticist

Series: AD-0401/0405/1320/0660

Location(s): Silver Spring, MD

Salary: $112,015 - $171,576

Work Schedule: Full Time

Cures Band(s): Band 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 mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over the counter and prescription drugs, including biological therapeutics and generic drugs.

The Office of Generic Drugs (OGD) oversees the development and implementation of standards for the safety and effectiveness of generic drugs. OGD reviews and evaluates Abbreviated New Drug Applications (ANDAs) and their amendments or supplements and determines approvability. OGD establishes bioequivalence reviews, industry protocol and studies. OGD oversees all aspects of labeling submissions for ANDAs.

The Office of Bioequivalence (OB) ensures that submitted bioequivalence data meets rigorous scientific and regulatory standards to support approval of high quality, affordable generic drugs.

The Divisions of Bioequivalence I (DBI), II (DBII), III (DBIII) evaluates in vivo and in vitro bioequivalence data and protocols in Abbreviated New Drug Applications (ANDAs) and their supplements and amendments as per the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments), section 505(j) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Duties/Responsibilities

As a **Pharmacokineticist**, the incumbent conducts the scientific evaluation of generic drug products and determines the acceptability of scientific and regulatory applications through the assessment and evaluation of submissions. Specific duties include, but are not limited to:

- Conducts the scientific evaluation of generic drug products; assesses, evaluates, and determines the acceptability of scientific and regulatory submissions and applications following an established process and within a specified timeline. Perform consultations to other offices within CDER to support OGD's mission, as needed.
- Applies knowledge of pharmacokinetic studies and in vitro and in vivo modeling approaches that predict the pharmacokinetic properties of drug products to reviews and evaluations of approvability of regulatory submissions.
- Reviews and assesses the scientific studies related to scientific aspects of bioequivalence data submitted as it relates to generic drugs and areas of pharmacokinetics including drug absorption, disposition, metabolism, and elimination as well as pharmacodynamic assays.
- Provides master knowledge in pharmacokinetic and drug metabolism, determining and delineating their role in the biological system being evaluated.
- Provides primary assessment of the results of pharmacokinetic, pharmacodynamics, bio-pharmaceutic and/or comparative clinical analyses of bioequivalence/bioavailability studies, especially studies conducted using generic drugs in ANDAs.
- Provides recommendations for approval, or identifies deficiencies or the need for additional

data, in the demonstration of bioequivalence in ANDAs, amendments, and supplements.

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:

Biological Science Series, AD-0401:
Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. For more information, please see: OPM Occupational Series Qualification Requirements, 0401

Pharmacology Series, AD-0405:
Degree: major in appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology. For more information, please see: OPM Occupational Series Qualification Requirements, 0405

Chemistry Series, AD-1320:
Degree: physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics. For more information, please see: OPM Occupational Series Qualification Requirements, 1320

Pharmacy Series, AD-0660:
Degree: Doctoral degree in Pharmacy. For more information, please see: OPM Occupational Series Qualification Requirements, 0660

Desired Professional Experience:
Our ideal candidate will possess:

- Ability to coordinate the work of external collaborators to accomplish organizational goals.
- Experience assessing, analyzing, or evaluating study designs, data or conclusions associated with ANDAs.
- Demonstrated ability to identify and analyze complex data and evaluate alternative solutions.
- Experience designing and recommending studies concerning specific drug issues.
- Successful ability applying formulations and dosage forms.
- Experience communicating effectively orally, in writing, and visually.
- Ability to organize time effectively, determine priorities, 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 qualifications is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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

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

Submit resume or curriculum vitae with cover letter **by May 1, 2023** to: OBPMASTeam@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

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

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