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 New Drugs (OND)

Application Period: November 12, 2021 – December 12, 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: Interdisciplinary Scientist

Series: AD-0401/0405/0415

Location(s): Silver Spring, MD

Salary: Starting at $103,690

Work Schedule: Full Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

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 are 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of New Drugs's (OND) public health mission is to protect and enhance the health of the public through the review and evaluation of scientific data submitted by pharmaceutical manufacturers in support of both New Drug (NDA) and Investigational New Drug applications (INDAs), and to determine if candidate drugs are safe and effective.

Duties/Responsibilities

The Interdisciplinary Scientist reviews and evaluates drug applications and communicates conclusions with a multidisciplinary review team. Reviews nonclinical data and communicates safety findings, evaluates nonclinical sections of product labeling, makes regulatory recommendations, and meets with industry representatives. Serves as a CDER resource for nonclinical safety assessments participating in work groups or subcommittees.

The functions of this position can be performed within any of the pharmacology/toxicology or clinical drug review divisions located within OND. The nature of the work can be performed by persons with education and experience in molecular, cellular or systems biology, pharmacology, and toxicology. The incumbent reviews in silico, in vitro, ex-vivo and animal data submitted to IND Applications, NDAs, and Biological License Applications (BLAs) to evaluate (1) mechanism of action (MOA) as proof-of-activity for use of medicinal products in patients, and (2) safety of medicinal products for use in patients and healthy subjects.

Use nonclinical data to recommend a first-in-human (FIH) dose range that is safe within the clinical trial context and therapeutic in patients. Employs advanced scientific knowledge for human dose selection that integrates medicinal products' pharmacology, molecular and cellular biology, systems biology, and safety profile. Mathematical modeling may be employed for human dose selection, as needed. Communicate conclusions on the FIH dose range and the clinical limit dose to the multidisciplinary review team and proposes clinical safety monitoring based on nonclinical data. Review nonclinical data throughout the drug development process and communicate any new safety findings to the FDA review team, in a formal or informal format. Evaluate specialized nonclinical studies such as animal efficacy studies via the Animal Rule for medical countermeasures.

Provide comprehensive summary and integrated evaluation of the nonclinical data submitted in INDs (and amendments), NDAs, and BLAs (and supplements) are prepared for supervisory concurrence. Other available information relevant to the assessment (e.g., published literature, genomic and other databases, quantitative structure-activity relationship) is incorporated into the evaluation, as appropriate. Conclusions are integrated with the conclusions of other team members. Evaluate whether nonclinical sections of product labeling have accurate and

adequate information to communicate the safety and risks of use to patients. Information in the product labeling to be evaluated include but are not limited to genotoxicity, carcinogenicity, and reproductive safety (fertility, embryofetal, and postnatal development) of the drug, and duration of contraception where applicable. Collaborate with other Divisions or Offices and Centers, as appropriate. Meet with industry representatives to discuss nonclinical studies needed in support of INDs, NDAs, or BLAs and to provide advice and guidance for product development regarding those aspects of the application that are within the area of activity/proof-of-concept, animal studies, and safety assessment.

Make regulatory recommendations, such as clinical hold (INDs) and drug approval (NDAs/BLAs) decisions, based on nonclinical data. In making regulatory decisions and providing internal and external recommendations, the Reviewer follows FDA and ICH guidance documents and internal practices and policies, and thus has knowledge of disease-specific, nonclinical, and multi-disciplinary guidance documents. Make determinations as to whether the nonclinical studies support continued drug development in the patient population being studied.

Attend meetings, conferences, and symposia of scientific organizations to remain aware and gain an understanding of developments in the field, to exchange ideas with scientific peers engaged in related areas, and to acquire information pertinent to the conduct of Divisional responsibilities.
Attend courses related to the development of medicinal products. Apply scientific and regulatory knowledge to address critical and novel problems, and extends and modifies approaches, precedents, and methods to solve a variety of issues related to drug safety. Serve as a CDER resource for nonclinical safety assessment by participating in specialized working groups or subcommittees. Perform other specialized duties related to safety assessment of medicinal products and their composition as assigned.

Supervisory Responsibilities: None

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 Cure's 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:

General Natural Resources Management and Biological Sciences Series, 0401

Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. **Or** Combination of education and experience: Courses equivalent to a major plus appropriate experience or additional education.

Pharmacology Series, 0405

Degree: major in an 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.

Toxicology Series, 0415

Degree: toxicology; or an appropriate discipline of the biological, medical, or veterinary sciences that included at least 30 semester hours in chemistry, biochemistry, or physiology, and 12 semester hours in toxicology.

Desired Education:

Candidates with doctorate degree and specialized experience in neuroscience, immunology,

pathology, cancer/molecular biology, or ophthalmology from an accredited university are highly encouraged to apply.

Professional Experience:

- Knowledge and experience in molecular, cellular or systems biology, pharmacology, and toxicology.
- Experience in scientific methods and techniques related to the non-clinical data, pertinent laws, regulations, and Agency policy.
- Demonstrated experience in evaluating and integrating data from multiple sources.
- Mastery knowledge of scientific methods and techniques related to the nonclinical data, pertinent laws, regulations, and Agency policy.

Desired Professional Experience: None

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:

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 these 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.

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 December 12, 2021 to CDER-ONDPharmTox.Employment @fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact Sharon Miller, Sharon.Miller@fda.hhs.gov. Please reference Job Reference **Source Code ID: 21-041LIN** in the subject line.

Announcement Contact

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

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