



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)
Office of Infectious Diseases (OID)
Division of Pharmacology Toxicology for Infectious Disease (DPTID)

Application Period: December 18, 2023 - December 29, 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.

Position: Toxicologist

Series: AD-0415

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 New Drugs (OND) is a super office within CDER responsible for the assessment of new drugs and therapeutic biologics. OND provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

The Office of Infectious Diseases (OID) evaluates for safety and effectiveness and approves New Drug Applications (NDAs) and Biologic Licensing Applications (BLAs) for products regulated by this Office of Infectious Diseases and evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based.

The Division of Pharmacology Toxicology for Infectious Diseases (DPTID) reviews and evaluates non-clinical pharmacology and toxicology data in Investigational New Drug Applications (INDs) and formulates appropriate action; and provides recommendations for approval or disapproval of research plans and protocols, modifications, and restrictions as needed. Reviews and evaluates the nonclinical pharmacology and toxicology data in New Drug Applications (NDAs) and Biological License Applications (BLAs) and formulates recommendations regarding approvability in accord with applicable delegations of authority.

Duties/Responsibilities

As a **Toxicologist**, the incumbent will primarily administer, advise on, supervise, or perform research, analytical, advisory, or other professional and scientific work in the discipline of toxicology. The standard statement of duties and the functions of this position can be performed within any of the toxicology review divisions located within the Office of New Drugs (OND).

- Reviews *in silico*, *in vitro*, *ex-vivo*, and animal data submitted to investigational New Drug Applications (INDs), New Drug Applications (NDAs), and Biological License Applications (BLAs) to evaluate: (1) the mechanism of action (MOA) as proof-of-activity for use of medicinal products in patients; and (2) the safety of medicinal products for use in patients and healthy subjects.
- Uses non-clinical 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.
- Communicates 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.
- Reviews non-clinical data throughout the drug development process and communicate any new safety findings to the FDA review team, in a formal or informal format, as needed. Evaluates specialized non-clinical studies, such as animal efficacy

studies via the Animal Rule for medical countermeasures, as needed.

- Provides comprehensive summary and integrated evaluation of the non-clinical 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 and combined with those of other team members.

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:

Toxicology, AD-0415 Series:

Education: A bachelor’s degree or higher in toxicology, pharmacology, environmental sciences, medicinal chemistry, pharmaceutical sciences, or related sciences. The degree must be from an accredited program or institution.

OR

American Board of Toxicology certification

Desired Professional Experience:

Our ideal candidate will possess:

- Knowledge and experience in 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.

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.

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 with cover letter by **December 29, 2023**, to: rosanna.alston@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”.

Please reference Job Reference ID: **OND-OID-DPTID-001** in the e-mail subject line.

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 rosanna.alston@fda.hhs.gov.

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

FDA is an equal opportunity employer.

