



**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 New Drug Products (ONDP)**  
**Division of Biopharmaceutics (DB)**

**Application Period:** October 21, 2021 – November 4, 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.

Commissioned Corp Officers are eligible to apply.

**Position:** Biopharmaceutics Reviewer  
(Interdisciplinary Scientist)

**Series:** AD-405/415

**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 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 New Drug Products (ONDP) is OPQ's focal point for the evaluation and assessment of Investigational New Drugs (INDs) and original New Drug Applications (NDAs) submissions, and Active Pharmaceutical Ingredient (API) information supporting Abbreviated New Drug Applications (ANDAs). The Division of Biopharmaceutics (DB) is responsible for evaluating and assessing relevant biopharmaceutics information in INDs, NDAs, ANDAs, supplemental ANDAs (sANDAs) and supplemental NDAs (sNDA).

### Duties/Responsibilities

The Biopharmaceutics Reviewers are responsible for reviews of in silico, in vitro, and human PK data submitted to INDs, NDAs, ANDAs, sNDAs, and sANDAs to evaluate the mechanism of action (MOA) as proof-of-activity for use of medicinal products in patients, the safety of medicinal products for use in patients and health subjects, and the quality profile of medicinal products in patients in order to recommend approval of applications.

- Reviews nonclinical and manufacturing/quality data throughout the development process and communicates findings.
- Evaluates specialized biopharmaceutical studies and regulatory recommendations.
- Evaluates whether biopharmaceutics/quality sections of NDAs, ANDAs, and/or BLAs (and supplements) are adequate with regard to information to communicate the safety and risks of use to patients.

**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 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.

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:**

Pharmacologist, 405: 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.

Toxicologist, 415: 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.

For more information please see: [OPM Occupational Series Qualification Requirements](#)

### **Desired Professional Experience:**

- Experience in developing research projects to fill gaps in knowledge related to pharmacology and toxicology.

- Experience in designing, developing, and validating the review protocols to evaluate the pharmacology and/or toxicology of regulated compounds such as drugs, chemicals, or tobacco.
- Experience in the evaluation of nonclinical pharmacology and/or toxicology studies.
- Knowledge of disease-specific, nonclinical, and multi-disciplinary guidance documents.
- Experience with written and oral communication techniques to develop reports and presentations.
- Experience establishing and maintaining effective relationships with customers, information sources, and team members.

## 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

All qualified candidates should submit resume with cover letter and unofficial transcripts (if you have foreign transcripts please submit foreign transcript evaluation from an accredited company) by November 4, 2021 to: [OPQ\\_Cures\\_Recruitment@fda.hhs.gov](mailto:OPQ_Cures_Recruitment@fda.hhs.gov). Candidate resumes may be shared with hiring official 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 [OPQ\\_Cures\\_Recruitment@fda.hhs.gov](mailto:OPQ_Cures_Recruitment@fda.hhs.gov). Please reference Job Reference ID: **DB –**

**Biopharmaceutical Reviewer.**

**Announcement Contact**

For questions regarding this Cures position, please contact [Dominique.Mitchell@fda.hhs.gov](mailto:Dominique.Mitchell@fda.hhs.gov).

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

*FDA is an equal opportunity employer.*

