



Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner

Application Period: November 18, 2022 to January 13, 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: Senior Clinical Advisor for Mental Health **Series:** 0601, 0602

Location(s): Silver Spring, MD

Salary: Starting at \$168,914 for the 0601 Series; Starting at \$210,000 for the 0602 Series

Work Schedule: Full Time/Temporary NTE 2 Years

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: Up to 25%

Bargaining Unit: 8888

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 safe, and effective.

The Office of the Commissioner is responsible for the efficient and effective implementation of the Food and Drug Administration mission. As the Senior Clinical Advisor for Mental Health, the incumbent provides advice to the Commissioner and performs substantive work that cuts across major Agency-wide programs and activities.

Duties/Responsibilities

- Offers concrete technical suggestions for stimulating further product development, in coordination with FDA medical product centers and programs.
- Produces recommendations for the Commissioner and Sr. Leadership, and drafts externally facing communications to address identified gaps such as action plans, guidance, or other communications as appropriate.
- Consults outside experts in the clinical and patient communities, as well as outside industry, as part of the initial landscape analysis on barriers to product development.
- Briefs steering committees or stakeholder groups, obtains feedback, and incorporates suggestions into work products as necessary.
- Work products will provide a roadmap for FDA staff and outside SMEs to follow, will facilitate project management that is linked to known milestones and will result in actionable products to advance an optimal regulatory approach and framework to facilitate the development of mental health therapies.

Supervisory Responsibilities: Non-Supervisory

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. Public Trust Background Investigation required.

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:

0601 Series Requirement: Bachelor’s or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the [U.S. Department of Education](#) at the time the degree was obtained.

0602 Series Requirement: *Degree:* Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the [Council on Medical Education of the American Medical Association](#) ; [Association of American Medical Colleges](#) ; [Liaison Committee on Medical Education](#) ; [Commission on Osteopathic College Accreditation of the American Osteopathic Association](#) , or an accrediting body recognized by the [U.S. Department of Education](#) at the time the degree was obtained.

Desired Education for 0602 Series: A strong candidate will have completed a residency in internal medicine as well as fellowship in relevant specialty; the incumbent will also have experience in clinical trial conduct and oversight, medical products regulation and/or biopharma product development. **OR** A strong candidate might alternatively have a PhD or ScD in a scientific health field with demonstrated experience in clinical trial conduct and oversight, medical products regulation and/or biopharma product development. Doctorate degree in a scientific field related to medicine, public health, pharmacology, and health sciences.

Professional Experience: The incumbent in this position will need experience developing a regulatory approach and framework to facilitate the development of mental health therapies; and conducting a comprehensive landscape analysis and assessment to include existing therapeutic options, key gaps or deficiencies, pipeline products.

Desired Professional Experience: Our ideal candidate will possess experience participating in

and contributing to top level Office, Center, Agency, PHS and Department discussions, meetings and conferences related to mental health therapy policies, programs, projects, and legislative initiatives.

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: This position requires a Public Trust Background Investigation.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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

How to Apply: Submit resume or curriculum vitae with cover letter by January 13, 2023 to: Ashley Crawford at Ashley.Crawford@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Office of the Commissioner with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions, please contact Tristan Colonius, Tristan.Colonius@fda.hhs.gov. Please reference Job Reference ID: T21-OCIO-2022-MH

Announcement Contact

For questions regarding this Cures position, please contact Tristan Colonius at 301-796-2624.

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

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