



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 Drug Evaluation Science (ODES)
Division of Clinical Outcome Assessment (DCOA)

This position is being recruited for using multiple job series: AD-601 and AD-602

Position: Division Director

Pay Plan-Series: AD-0601 and AD-602

Location(s): Silver Spring, MD

Travel Requirements: Up to 25%

Application Period: July 15, 2020-July 29, 2020

Salary: AD-601 Starting at \$162,339 (CURES Band F)
AD-602 Starting at \$210,000 (CURES Band F)

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

Special Notes: This position is being filled under an excepted 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 compensated under the provisions of the authority. [Additional information on 21st Century Cures Act can be found here.](#)

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 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 and prescription drugs, including biological therapeutics and generic drugs. CDER is looking for leaders with a commitment to scientific excellence and innovative thinking to lead a dynamic and diverse organization. The Office of New Drugs (OND) is conducting a search for talented leaders for the position of **Division Director** in the **Division of Clinical Outcome Assessment (DCOA)**.

OND is a dynamic, purpose-driven organization dedicated to the review of new drug applications, interactions with the pharmaceutical industry and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multi-disciplinary organization engaged in the oversight of human drug trials in the United States, in review of new drug applications (NDAs) and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over-the-counter (OTC) drug products.

Position Summary:

The Director of DCOA will provide direction, oversight, and leadership to multi-disciplinary experts that promote the development and implementation of Clinical Outcome Assessments (COAs) as drug development tools (DDT) to foster drug development. The incumbent of this position will actively engage with internal and external stakeholders to advance the development of scientific standards and policy for COAs as well as lead the development and implementation of good measurement standards in clinical trials.

The Director will serve as an advocate and lead for excellence in health measurement, international harmonization of standards for patient reported outcome (PRO) measurement, and the COA DDT qualification program.

The Director will provide consultation and advice to OND review divisions and other FDA Centers on COA development, validation, and interpretation as effectiveness endpoints in clinical trials for IND, NDA, and BLA submissions.

Supervisory responsibilities:

As Division Director, the incumbent will supervise and evaluate staff who serve as experts in their field, provide occupational specific technical and administrative direction and supervision to subordinate supervisors and staff.

Professional Experience/Desirable Qualifications: AD-601

- Experienced and effective communicator who can drive collaboration, empower staff, provide expert advice and consultation, coordinate program activities, and spearhead important program initiatives.
- Demonstrated experience in leadership principles and concepts.
- Possession of significant experience in managing and leading a diverse interdisciplinary staff.

Desired Educational Requirements:

A Ph.D., or equivalent degree, in a relevant subject such as in psychology, neurobehavioral science, or social science from an accredited graduate school.

Minimum Educational requirements include:

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 \(external link\)](#) at the time the degree was obtained.

Professional Experience/Desirable Qualifications: AD-602

- Experienced and effective communicator who can drive collaboration, empower staff, provide expert advice and consultation, coordinate program activities, and spearhead important program initiatives.
- Demonstrated experience in leadership principles and concepts.
- Possession of significant experience in managing and leading a diverse interdisciplinary staff.

Minimum Educational requirements include:

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.

Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates, a fifth pathway certificate for Americans who completed premedical

education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

Licensure

For all band levels and positions, applicants must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

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. [Click here to find out additional information about the Equal Employment Opportunity \(EEO\) for federal employees & job applicants.](#)

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 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](#).

Conditions of Employment:

Security Clearance: This position requires a Public Trust security clearance and the incumbent has access to sensitive, proprietary, or financial information.

Ethics Requirements:

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at <https://www.fda.gov/about-fda/jobs-and-training-fda/ethics>.

How to Apply: Please submit resume or curriculum vitae with cover letter to: cdler-ond-leadership-employment@fda.hhs.gov. For questions please email: cdler-ond-leadership-employment@fda.hhs.gov. **Please reference source code: OND-DCOA-100 in the subject line of your submission**

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