



**Data Scientist and Associate Director for Advanced Technologies  
Department of Health and Human Services (DHHS)  
Food and Drug Administration (FDA)  
Center for Biologics Evaluation and Research (CBER)  
Office of Biostatistics and Pharmacovigilance (OBPV)  
Immediate Office of the Director (IOD)**

**Summary**

The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Pharmacovigilance (OBPV) and being filled under FDA’s Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA’s ability to recruit and retain scientific, technical, and professional experts in certain occupational series that “support the development, review, and regulation of medical products.” The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

***Become a part of the Department that touches the lives of every American.***

*At the [Department of Health and Human Services \(HHS\)](#) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.*

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Biologics Evaluation and Research (CBER) is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

The mission of the Office of Biostatistics and Pharmacovigilance (OBPV) involves evaluating the safety and efficacy of the spectrum of CBER products throughout their entire lifecycle, from preclinical to post-marketing. OBPV scientific disciplines include experts in epidemiology, pharmacoepidemiology, medicine, genomics, statistics, risk analysis, public health, and related scientific areas.

**Overview**

Area of Consideration: The Public
Open & Closing Date: August 6, 2024 – August 12, 2024
Salary Range: \$163,964 - \$251,125 and is set commensurate with education and experience.
Band: E
Occupational Series: 0301

Duty Location: White Oak Campus, Silver Spring, MD
Remote Job: No
Telework Eligible: Yes – as determined by agency policy.
Travel Required: 25% or less
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band E
Supervisory Status: Non-supervisory
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 8888

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

## Duties

The incumbent serves as the Associate Director for Advanced Technologies in the Immediate Office of the Director (IOD) within the Office of Biostatistics and Pharmacovigilance (OBPV). This position reports to the Office Director of OBPV. The Associate Director for Advanced Technologies is responsible for providing scientific, strategic, and organizational leadership for advanced technologies, including data analytic initiatives. The incumbent provides technical expertise to office review staff in the development, implementation, and oversight of new advanced technologies related to OBPV review and surveillance activities.

Specifically, the Associate Director for Advanced Technologies will:

- Leads prioritization of understanding and application of advanced technologies, lead development of review and surveillance processes that incorporate new artificial intelligence methodologies, and assure statistical and scientific validity of guidance documents and outreach activities for these initiatives.
- Use advanced analytical techniques to develop computational algorithms and statistical methods that find patterns and relationships in large volumes of data; and develop findings, inferences, conclusions, and recommendations.
- Translate results of analysis into clear, actionable communications that equip Agency decision makers to make informed, data-driven decisions about data analytics and artificial intelligence development.
- Lead the Biologics Effectiveness and Safety (BEST) Initiative for Development of New and Innovative Methods for Automated Reporting for CBER-Regulated Biological Products, that obtain computable phenotypes of patients representing biologic product exposure/adverse event (AE) pairs from health records.
- Lead and manage programs and large contracts for advance technologies, providing overall strategic direction for advance technology areas by developing solutions and applications to address regulatory needs in the context of an evolving regulatory landscape for new technologies.
- Solve technical problems by writing code and explaining data architecture and design to both technical and non-technical audiences; deliver reports and relevant information to support the needs of leadership and product teams.
- Identify requirements, expected outcomes for new or existing initiatives, and the measurements of success for advanced technology programs.
- Identify and assess emerging complex program operations and management issues and advise OBPV Director, internal and external stakeholders of potential and emerging problem areas and strategies for issue resolution for advanced technology.
- Serve as the OBPV expert in advanced technology, provide information and consultation to individuals, federal agencies, private industry, universities, and/or foreign governments on consumer safety issues.

- Represent CBER at meetings, workshops and Agency and Department discussions concerning advanced technology. Coordinate and communicate program initiatives and outcomes with CBER and FDA leadership.
- Prepare and give presentations concerning the application of advanced technology for biological product review and surveillance to state, local, and foreign governments, subject matter experts, upper levels of management, industry, and academia.
- Perform other duties as assigned.

## Requirements

### Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- 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. Please go to <http://www.sss.gov> for more information.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: 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.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- **If you are serving, or have served in the last 5 years as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. See [Political Appointee FAQ - OPM](#) for more.

## Qualifications

### Basic Qualification Requirements:

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:** A bachelor’s degree or higher in mathematics, statistics, computer science, informatics, data science, engineering, operations research, bioinformatics, economics, public health, computational biology, physics, or related scientific or technical field. The degree must be from an accredited program or institution.
- **OR**
- **Experience requirements** Comparable work in or demonstrated understanding in data science or a related field (through portfolios, certifications, etc.).

Desired Professional Experience, Skills, and Education:

- Knowledge and experience with machine-learning, artificial intelligence, natural language processing, robotics, and other methods to develop and automatically generate post-market safety reports as well as applications of digital health technologies for the monitoring and evaluation of CBER-regulated products.
- Demonstrated experience in written and oral communications techniques required to prepare and deliver reports and presentations on study results and other critical data and information.
- Experience using concepts, principles, and practices related to data management, data reliability, data validity, and data analysis.
- Demonstrated experience communicating highly technical information in a clear matter.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.

Education must be accredited by an accrediting institution recognized by the [U.S. Department of Education](#) in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by the U.S. Department of Education.

**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 further information, visit the [U.S. Department of Education website for Foreign Education Evaluation](#).**

How you will be Evaluated: You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement. Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

## How to Apply

Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), SF50 (if applicable), copy of unofficial transcripts, latest PMAP (if applicable), and letter of interest with **“CURES CBER/OBPV/IOD Associate Director for Advanced Technologies”** in the subject line to: [CBERHumanCapital@fda.hhs.gov](mailto:CBERHumanCapital@fda.hhs.gov). Applications will be accepted through **August 12, 2024**.

## Announcement Contact

For questions regarding this Title 21 Cures position, please contact [CBERHumanCapital@fda.hhs.gov](mailto:CBERHumanCapital@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.*

