



**Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)
Office of Clinical Evidence and Analysis (OCEA)**

Position(s): Artificial Intelligence Advisor

Location(s): Silver Spring, Maryland, FDA headquarters, [White Oak Campus](#)

Travel Requirements: This position may require up to 25% travel.

Application Period: Thursday, May 19, 2022, through Thursday, June 16, 2022

Salary: Salary starts at \$148,484.00 and is commensurate with experience

Conditions of Employment: United States Citizenship is required

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 be paid under the provisions of the authority. [Additional information on 21st Century Cures Act can be found here.](#)

Introduction: The [Center for Devices and Radiological Health \(CDRH or Center\)](#) assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. The [Office of Product Evaluation and Quality \(OPEQ or Office\)](#) facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

The [Office of Clinical Evidence and Analysis \(OCEA or Office\)](#), within OPEQ, provides policy and programmatic support for clinical trials, the protection of human subjects, biostatistics, real-world evidence, epidemiological analysis and outreach, and collaborates with hospitals, health systems, industry, and other external stakeholders. Additionally, OCEA provides regulatory oversight of medical device clinical investigations, to ensure good laboratory practices and clinical practices in support of premarket review. Further, OCEA oversees the application of modern artificial intelligence (AI) tools, including machine learning (ML) algorithms and deep learning methodologies that can be evaluated, piloted, and implemented at scale, by CDRH, to identify or predict medical device safety signals faster and earlier in the life cycle of devices.

Position Summary: OCEA is seeking an experienced Artificial Intelligence Advisor. In this position, you will report to the OCEA Deputy Office Director and will be charged with advancing the Office's strategic vision for the development and implementation of AI and ML initiatives that support OCEA and OPEQ in the TPLC review of medical devices. In leading this Center-wide effort,

you will develop a strategic vision, provide technical direction, and assure the successful systematic operational implementation of these AI and ML modeling and design data science initiatives. You will also serve as the Center's AI and ML Liaison. As such, you will champion this technology and provide the necessary guidance, leadership, and support to all components of CDRH, to ensure the Center is well-positioned to positively embrace this implementation. Further, you will represent the Office and Center and collaborate with external stakeholders and exchange information and ideas with other AI and ML experts associated with the development and use of this enabling technology.

Duties/Responsibilities: As the Artificial Intelligence Advisor, you will:

- Direct the strategic vision, direction, and AI and ML implementation strategies for the OCEA and the Center.
- Develop executive-level and technical briefing materials to convey AI and ML strategies to multiple audiences, which identify metrics, performance indicators, and milestones to monitor progression.
- Lead and support Data Scientists in the development of scalable data science solutions and tools to address business needs, including reporting, analytics, and experimentation platforms.
- Empower senior Data Scientists, through collaboration, to determine the proper data insights to generate data-driven decisions.
- Provide oversight of the integration of in-depth data science knowledge into analytics and visualization tools that will be utilized to support Office and Center leadership, as well as the scientific and technical staff in evidenced-based regulatory decision making.
- Provide technical expertise to product teams in the development, implementation and oversight of new technologies in the field of Data Science.
- Establish, refine, and lead long-range strategies, with feedback loops, for data governance, analytical insights, and ML, to drive data-centered thinking and to ensure innovative techniques are embedded throughout the process.
- Share technical expertise with product teams regarding the development, implementation and oversight of new technologies in the field of Data Science.
- Establish and sustain a strong and dynamic environment within the Division and Office to support organizational agility, innovation, a focus on continuous improvement, mentorship, staff empowerment, and collaboration.
- Serve as the Center's AI and ML External Partnership Liaison and engage with external stakeholders leading similar initiatives to identify strategic alignment and opportunities to integrate and share best practices in developing and deploying emerging AI capabilities to ensure business needs are being met.
- Represent the Office at meetings, advisory panels, and conferences and brief attendees on technical issues, provide explanations and interpretations of decisions, and share OCEA's activities, plans, and policies.
- Employ quality assurance and quality control protocols to gauge and improve effectiveness, uncover and analyze data discrepancies, and develop strategies to promote data quality and integrity.

Professional Experience/Key Requirements: To qualify for this position, you must demonstrate in your resume the necessary qualifying experience, which includes the following:

- Experience in developing, leading, implementing, and evaluating large-scale AI and ML strategies.
- Experience in leading interdisciplinary scientists, clinicians, and other regulatory professionals in large-scale science-based organizations.

- Leading the strategic achievement of organizational goals, evaluating organizational performance, and taking action to improve outcomes.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Skillful in effectively interpreting and presenting complex scientific, technical, and regulatory information and concepts, in both written and oral formats, for a variety of audiences.
- Experience in utilizing predictive modeling concepts, machine-learning approaches, and/or optimization algorithms to analyze data.
- Expertise in machine learning, deep learning (CNNs, RNNs, LSTMs, GANs), and familiarity with deep learning libraries (TensorFlow, PyTorch, etc.).

Desirable Education and Experience:

- Applicants with advanced degrees in Biomedical Engineering, Computer Engineering, Electrical Engineering, General Engineering, Systems Engineering, Computer Science, Mathematics, Mathematical Statistics, Statistics, or related fields.
- Prior experience in a scientific, regulatory, or medical device manufacturing setting.
- Ability to work collaboratively with a diverse cadre of colleagues and stakeholders in a continuous quality improvement ecosystem.

Basic Qualifications:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: <https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series>

Conditions of Employment:

- A probationary period may be required.
- Background and/or Security investigation required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the [Selective Service System](#) OR have an approved exemption.
- 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. For additional information on the prohibited financial interests, visit the FDA Ethics and Integrity Office website at <https://www.fda.gov/about-fda/jobs-and-training-fda/ethics>.

How to Apply: Submit an electronic resume or curriculum vitae, cover letter containing a brief summary of scientific accomplishments, and a copy of unofficial transcripts all in one document (Adobe PDF) to CDRHRecruitment@fda.hhs.gov, with Job Reference code “**2020-OCEA-DCEA1-040-2021-11-29D**” in the subject line. Applications will be accepted through **June 16, 2022**.

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 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](#).

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