TITLE 21 VACANCY ANNOUNCEMENT

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)
Division of Clinical Evidence and Analysis II (DCEA2)

Position(s): Sr Data Scientist, CDRH/OPEQ/OCEA/DCEA2

Series: The position of may be filled by candidates from the following occupational series: Data Scientist (301), General Engineer (0801), Computer Engineer (0854), Mathematics (1520), Mathematical Statistician (1529), Statistician (1530), and Computer Science (1550)

Location(s): Remote Eligible

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

Application Period: Thursday, March 2, 2023, through Wednesday, March 29, 2023

Salary: Salary starts at $126,233 and is commensurate with experience

Conditions of Employment: U.S. 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. CDRH 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.

Within CDRH, the Office of Product Evaluation and Quality (OPEQ or Super Office) is responsible for setting strategy and overseeing the Offices of Health Technology 1-7, Office of Clinical Evidence & Analysis (OCEA or Office), Office of Regulatory Programs (ORP). Using a focused Total Product Lifecycle (TPLC) approach, the Office ensures quality end-to-end device evaluation and the consistent interpretation and application of regulatory policy and guidance. The Office ensures that these activities are aligned to the overall strategy and priorities of CDRH and FDA and contains staff responsible for Clinical Affairs, Quality Management and Analysis, and Strategic Initiatives.

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 innovative, forward thinking and driven Data Scientist(s) to develop, pilot, and implement various data analytics tools within CDRH, while collaborating with a team of Data Scientists, Data Engineers and Developers across the Office and Center and interfacing with contractors to accomplish these goals.

Duties/Responsibilities: As a Senior Data Scientist, the selected candidate will:

- Serve as a subject matter expert and provide administrative and technical oversight on the integration of in-depth data science knowledge into data analytic and visualization tools that will be utilized to support Office and Center leadership in making evidenced-based regulatory decisions concerning digital health devices, encompassing the entire product lifecycle.
- Provide expert guidance and share recommendations, with Team, Division, and Office leadership, on cloud-based solutions and custom software to support regulatory technology integration needs.
- Advises the Deputy Division Director, Deputy Office Director, and other leadership on the utilization of new and emerging technologies associated with artificial intelligence and machine learning in the analysis of medical device data to detect early signals, trends, and other critical information that may not be visible upon routine inspection.
- Identify risks and encourage continuous improvements in data management through technological innovation and operational improvement.
- Analyzes data sets to determine their quality and informational content and cleanses them to maintain their use in regulatory analysis and decision-making.
- Forge mutually beneficial formal partnerships with medical device stakeholders, foreign agencies, professional and scientific organizations, health care community, patient advocacy groups, academia, and other federal, state, and local stakeholders.
- Apply expert knowledge of development, support, and analysis of data systems, including evaluating their effectiveness and determining appropriate enhancements to support the duties and responsibilities of the position.
- Keep abreast of evolving and state of the art regulatory policies and procedures and data/information science, data tools, and best practices
- Solve complex analytical problems using quantitative approaches. Lead cross-functional teams, which includes product owners, designers, developers, researchers, and content editors, to develop data-driven solutions to address business and user challenge
- Communicate data findings to stakeholders using different visual formats to picture and provide reports. Provide technical expertise to Deputy Division Director and members of product teams in the development, implementation, and oversight of new technologies.

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

- Leading large-scale enterprise data and information technology projects and programs.
- Solution focused Data Scientist with expertise in data management, reporting technologies, and knowledge of emerging technologies, such as databases, predictive analytics, and data visualization.
- Knowledge of development, support, and analysis of data systems, including evaluating their effectiveness and determining appropriate enhancement to support the duties and responsibilities of the position.
- Ability to analyze and interpret regulatory policy and guidance to share expertise and advise leadership on highly complex and precedent setting public health matters.
- Have wide-ranging technical expertise in medical device infrastructure development and implementation, business analytics, and modeling.
- Ability to effectively communicate through memoranda, position papers, and presentations to senior leaders and other clinical, engineering, technical, and scientific experts.
- Experience in developing, documenting, and promoting the components of data governance and analysis best practices. Expertise in using open-source programming languages such as Python to manipulate and analyze data
- Ability to utilize predictive modeling concepts, machine learning (ML) approaches, and/or optimization algorithms to analyze data.
- Experience with training ML models under data-starved conditions
- Experience with domain adaptation methods
- Previous expertise in one or more of ML, deep learning (CNNs, RNNs, LSTMs, GANs), and familiarity with deep learning libraries (TensorFlow, PyTorch, etc.)

Desirable Qualifications/Experience:

- Skillful in effectively interpreting and presenting complex information and concepts, in both written and oral formats.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Ability to actively embrace diversity by actively promoting an inclusive workplace that maximizes the talents of each person.
- Ability to focus on objectives and results when considering the various alternatives to a decision.

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.
- Due to COVID-19, the Agency is currently in an expanded telework posture. If selected, you may be expected to temporarily telework, even if your home is located outside the local commuting area. Once employees are permitted to return to the office, you will be expected to report to the duty station listed on this announcement within 45 days. At that time, you may be eligible to request to continue to telework one or more days a pay period depending upon the terms of the agency's telework policy. As required by Executive Order 14043, Federal executive branch employees are required to be fully vaccinated against COVID-19 regardless of the employee's duty location or work arrangement (e.g., telework, remote work, etc.), subject to such exceptions as required by law. If selected, you will be required to be vaccinated against COVID-19 and will receive instructions on how to provide documentation.

How to Apply: Submit an electronic resume or curriculum vitae, a 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-DCEA2-MDE-019/ PBM-4139 and 2020-OCEA-DCEA2-043/PBM-3864"** in the subject line. Applications will be accepted through **March 29, 2023.**

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 factors.

- 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.

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