Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Innovation (OST)
Division of Digital Health (DDH)

****This announcement may be used to fill multiple positions****

Position(s): Data Scientists (Digital Health Specialists)

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

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

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

Application Period: Thursday, September 16, 2021, through Friday, October 15, 2021

Salary: Salary starts at $122,530.00 and is commensurate with education and experience

Conditions of Employment: U.S. Citizenship or permanent U.S. residency 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 Strategic Partnerships and Technology Innovation (OST or Office) provides leadership for all scientific, collaborative, and emerging technology activities. OST represents the Center and collaborates with a broad and diverse array of national and international entities, with mutual interests in medical devices, combination products, and radiation-emitting diagnostic equipment, including other government agencies, Congress, industry, academia, consumer and patient organizations, and healthcare professional organizations.

Data Science is revolutionizing the development of digital diagnostics and therapeutics, and advancements in the field promise to improve medical device regulation and oversight as well. CDRH is excited about these advances and the convergence of medical devices with

connectivity and consumer technology and has established the Digital Health Program to develop innovative new approaches to regulating these technologies. Data Scientists in the Digital Health Center of Excellence help FDA evaluate digital health medical devices and help FDA develop decision support tools and data pipelines to improve the evaluation of digital health medical devices.

Position Summary: CDRH is seeking innovative, forward thinking, and driven Data Scientist(s) to join our Digital Health Program. In this position, you will report to the Assistant Director for Emerging Digital Health Technology Assessment and Strategy and will be responsible for planning, leading, and coordinating all data science related activities for the Digital Health Program.

Duties/Responsibilities: As a Digital Health Data Scientist, you 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.
- Engage and educate the Digital Health Division and Office leadership on data as an integral enterprise asset within the current ecosystem and the importance of proper data governance, management, and stewardship.
- Advises the Assistant Director, Division Director, and Office leadership on the utilization of new and emerging technologies associated with artificial intelligence and machine learning in the analysis of digital health 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 manufacturers, suppliers, carriers, foreign agencies, professional 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.
- Drive the effort to reduce industry's administrative burden, continuously streamline technology, supporting product development, and facilitating innovation, without compromising the regulatory review process.
- Draft recommendations, most of which will be technical in nature, to describe data science activities, analysis, results, and conclusions to assist in supporting and advancing digital health medical device regulation.

Professional Experience/Key Requirements:

To qualify for this position, you must demonstrate in your resume the necessary qualifying experience, which includes 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.

Desirable Education:

- Applicants with degrees in computer science, computer engineering, cybersecurity, engineering, mathematics, or related field.
- 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 meet the educational and 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, SF-50 (if applicable), and a copy of unofficial transcripts all in one document (**Adobe PDF**) to CDRHRecruitment@fda.hhs.gov, with Job Reference code ***"2020-OST-DDH"*** in the subject line. Applications will be accepted through **October 15, 2021.**

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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FDA is an equal opportunity employer