U.S. FOOD & DRUG ADMINISTRATION

# 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 Regulatory Program (ORP)

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**Position(s):** Assistant Director (Supervisory Data Scientist)

**Series:** The position may be filled by candidates from the following occupational series: 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**: Monday, November 1, 2021, through Tuesday, November 30, 2021

**Salary:** Salary starts at $122,530.00 and is commensurate with education and 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 Food and Drug Administration (FDA or Agency) 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 safe, and effective.

The mission of CDRH is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States. OPEQ assures patients have access to high quality, safe and effective products throughout the total product lifecycle by implementing program areas through which medical devices are evaluated or cleared for clinical investigations and marketing.

The Office of Regulatory Programs (ORP or Office), within OPEQ establishes policy and provides support across a variety of premarket, post-market and compliance programs impacting the regulated medical device industry. The office performs cross-cutting analysis to assess the performance of programs, develops tools that aid in evaluating the safety and quality of devices and electronic

products, and continually monitors the state of the regulated medical device industry. This Office strives to amplify and improve the impact that Center activities have on patients by facilitating accurate, consistent, and timely assessment of medical and other technology over its full life.

**Position Summary**: ORP is seeking an innovative, forward thinking, and team oriented Assistant Director, with a specialization in Data Science, to lead the Office's Lifecycle Program Analytics Team (LPAT or Team). In this critical position, you will report to ORP's Division Director of Regulatory Programs III (DRP3 or Division) and will be responsible for planning, leading, and coordinating all data analytics activities, to include developing performance dashboards, decision memoranda and reports, and review tools to ensure the reliability of reported data and to assist in evidence-based decision making throughout the total product lifecycle of medical devices regulated by the Center.

**Supervisory Responsibilities:**
As a creative and collaborative leader, you will manage and grow a high-performing, multidisciplinary scientific, technical, and professional team in support of advancing the strategic vision of the Team and Office. As such, you will evaluate the technical performance of your team members who serve as experts in their respective fields and devote at least 25 percent of your time towards coaching, mentoring, and supervising your employees.

**Duties/Responsibilities:** As the Assistant Director of the LPAT, you will:

- Serve as a subject matter expert and provide oversight on the integration of in-depth data science knowledge into data analytic and visualization tools that will be utilized to support Division, Office, and Center leadership in making evidenced-based regulatory decisions concerning medical devices, diagnostic equipment, and combination products regulated by the Center.
- Conduct quantitative data analysis using a variety of datasets and methodologies, including retrieval, processing, fusion, analysis, and visualization of data to support CDRH reporting and data needs, which includes review performance analytics and market intelligence predictive analytics.
- Utilize new and emerging technologies associated with artificial intelligence and machine learning, to support the business needs of the Office in the collection, analysis, interpretation, and reporting of medical device data.
- Analyzes data sets to determine their quality, informational content, and cleanse to maintain their use in regulatory analysis and decision-making.
- As the authoritative voice for data science for ORP, you will collaborate with colleagues and leadership across the Division and Office to develop data analytical and assessment tools and corresponding guidance documents, policies, and procedures for consistency and transparency of use in the regulatory review process of medical devices.
- Collaborate in the development, coordination, and implementation of policies and programmatic norms rooted in science to assure medical products, especially those novel in nature, with emerging technologies, and within scope are safe, effective, reliable, and available for patients and providers.
- Engage and educate the LPAT, Division, and Office leadership on the importance of data as an integral asset within the current ORP ecosystem and the importance of proper data governance, management, and stewardship.
- Forge mutually beneficial formal partnerships with medical device manufacturers, foreign agencies, professional scientific organizations, health care community, patient advocacy groups,

academia, and other federal, state, and local stakeholders.
- Evaluate industry data to ascertain if mathematical and statistical methods, procedures, study design, and clinical claims presented are supported by validated statistical analysis.
- Develop assessment tools that examines study design methodology, evaluate endpoints, and assesses manufacturer diagnostic and therapeutic claims.
- Offer expert statistical and psychometric interpretations of statistical and psychometric interpretations design methodology and data captured in the development of technical reports and presentations
- Collaborates with Division leadership to plan, organize, and establish or realign priorities, assignments, and work projects to advance new initiatives and/or the programmatic and regulatory objectives of the Division and Office.
- Provide expert consultation to ORP leadership on programmatic plans, the healthcare and scientific communities, and industry related trends, significant concerns, and adverse event reported data regarding medical devices.
- Keep abreast of evolving and state of the art regulatory policies and procedures and data/information science, data tools, and best practices to understand and interpret medical device data.
- Draft decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, and reliability concerns.

**Professional Experience/Key Requirements:** To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which includes the following:
- Leading and completing large-scale enterprise data and information technology projects/programs.
- Solution focused data scientist with expertise in data management, reporting technologies, and knowledge of programming languages and emerging technologies, such as NoSQL databases, C/C++, Python, JavaScript, JSON, BusinessObjects, predictive analytics, and data visualization.
- Expertise in advanced analytics, modern machine learning and predictive techniques, such as random generalized linear modeling, decision trees, forests, boosted ensembles, and neural networks.
- Expertise in developing, documenting, and promoting the components of data analysis and governance best practices.

**Desirable Education and Experience:**
- Applicants with a Bachelor's, Master's, Ph.D., or an equivalent degree in computer science, cybersecurity, computer engineering, engineering, mathematics, or related fields.
- Prior experience in a scientific, regulatory, medical device manufacturing, or clinical setting.
- Ability to work collaboratively with a diverse cadre of colleagues and stakeholders in a continuous quality improvement ecosystem.
- Prior managerial experience or experience leading a team, preferred

**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, 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-ORP-DRP3-LPAT"** in the subject line. Applications will be accepted through **November 30, 2021**.

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