



## 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 Strategic Partnerships and Technology Innovation (OST)  
Division of Digital Health (DHT)**

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**Position:** Assistant Director (Supervisory Interdisciplinary Scientist)

**Series:** The position of Supervisory Interdisciplinary Scientist may be filled by candidates from the following occupational series: Physician (0602), Biologist (0401), Microbiologist (0403), General Health Scientist/Epidemiologist (0601), Nurse Consultant (610), Consumer Safety Officer (0696), Physical Scientist (1301), Physicist (1310), Chemist (1320), General Engineer (0801), Material Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858), Mathematical Statistician (1529), and Statistician (1530).

**Location(s):** Silver Spring, Maryland

**Travel Requirements:** This position requires occasional travel up to 25%.

**Application Period:** November 15, 2020, through December 4, 2020

**Salary:** Salary is commensurate with education and 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 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. Within CDRH, the Office of Strategic Partnerships and Technology Innovation (OST) provides leadership for all scientific collaborative and emerging technology related activities at the CDRH. The Division of Digital Health (DHT) provides oversight and leadership in the development, review, and implementation of regulations, policies, procedures and guidances related to software and digital health topics, and in the development of new legislation.

**Position Summary:**

Reporting directly to the Deputy Division Director, the Assistant Director provides authoritative and professional expertise in digital health technology and serves as an expert advisor and technical authority on complex and precedent-setting policy and program issues. The Director is responsible for the development of policies, strategies, and plans to facilitate growth and spur transformation of the digital health technology industry.

**Supervisory Responsibilities:**

The Assistant Director:

- Supervises a team of software experts primarily responsible for new program development related to digital health technology.
- Provides scientific and technical leadership and guidance for medical device and digital health matters before the Agency.
- Makes recommendations on issues which have the potential to significantly affect the development of digital health products.
- Serves as a source of expert advice for the Division of Digital Health staff.
- Develops and implements priorities, including implementing consistent benefit-risk decision-making, the consideration of uncertainty in such decisions, and development of novel pathways; for the review of digital health products.
- Directs the work of the team, assigns incoming matters, and provides first level signoff of work products.
- Leads the strategic achievement of team goals, evaluating team performance, and taking action to improve performance.

**Duties/Responsibilities:**

The Assistant Director performs the following:

- Serve as a technical and scientific consultant and advisor to the Director, Digital Health and provides expertise and consultation to engineers, scientists, industry representatives, consultants and clinical investigators on scientific, statistical, and regulatory aspects of digital health products to include machine learning and artificial intelligence.
- Provide information, advice, and consultation to government entities, federal agencies, private industry, and/or universities on unique and complex scientific or regulatory issues.
- Serve as an official representative and collaborates on a national level with scientists and government officials on a wide range of regulatory issues. Initiates, develops and disseminates guidance, policies, procedures and training materials for digital health technologies to include software as a medical device, the software pre-certification pilot program, machine learning and artificial intelligence.
- Exercise discretion, analytical skill, judgment and personal accountability and responsibility for developing research programs.
- Provide scientific expertise as well as specialized analytical expertise on a wide variety of regulatory issues and matters.
- Analyze and evaluate the implementation of new software and digital health policies that impact CDRH's mission and initiates analyses as it relates to advances in digital health technologies. (e.g., systems, software development, etc.).

- Analyze current and emerging business models related to digital health using input from investment community, industry, healthcare providers, patients, staff, and other stakeholders.
- Identify opportunities for innovation and assess the healthcare marketplace for obstacles and technical hurdles to the business success of digital health technologies.
- Represent the Center within and outside FDA on projects pertaining to digital health program requirements.

### **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](#).

### **Professional Experience/Key Requirements:**

To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which is equivalent to the following:

- Knowledge of medical device stakeholder and digital health stakeholders

- Excellent leadership and communication skills.
- Ability to work collaboratively with a diverse cadre of customers and stakeholders.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.

**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>

**Desirable Education:**

Applicants with an advanced degree in science, engineering, or medical fields are highly desired.

**Additional Conditions of Employment:**

- One-year 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, please visit the FDA Ethics and Integrity Office website at <https://www.fda.gov/about-fda/jobs-and-training-fda/ethics>.

**How to Apply:**

Prior to applying, please see the following instructions:

- Documents to submit: electronic resume or curriculum vitae, cover letter containing a brief summary of scientific accomplishments, and copy of transcripts
- Compile all applicant documents into **one combined document (i.e. Adobe PDF)**
- Include Job Reference code **“OST-DDH-2020-LKI-01”** in the email subject line.
- Email comprehensive applicant package/document to [CDRHRecruitment@fda.hhs.gov](mailto:CDRHRecruitment@fda.hhs.gov) by **Friday December 4, 2020**.

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

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