

DIGITALHEALTHADVISOR

Seeking Software Engineers, Health Scientists, Clinicians (www.fda.gov/digitalhealth)



At FDA, we are building a dynamic Digital Health Team whose mission is to protect and advance public health by helping to speed innovations that provide our nation with safe and effective Digital Health technologies. We are seeking candidates for multiple positions with a variety of expertise in delivering digital health technologies. This position is located on FDA's White Oak Campus in Silver Spring, Maryland.

By joining the Digital Health team, you will be at the forefront to advance medical science, create new opportunities and create a regulatory environment that bring safe and effective digital health technology to market. The Digital Heath Unit is a startup within the FDA's Center for Devices and Radiological Health (CDRH) that works collaboratively with internal and external customers to advance Digital health. We are an interdisciplinary group of experts pooling our technology, business, scientific and public health expertise to promote and protect public health. We are looking for digital health experts to join us on this exciting and cutting-edge healthcare transformation journey and lead as agents of change at FDA for the digital health future.

As a *Digital Health Advisor*, you will primarily serve as an expert who understands what it takes to develop, deliver, and maintain high quality digital health technologies during the FDA's review and evaluation of digital health technologies. Partnering with, internal subject matter experts, and external business and technology leaders, your goal is to stay current on technological advances, health benefits and risks, best practices and help in development of FDA Digital health policies and ongoing regulatory clarity.

Specific responsibilities include, but are not limited to:

- Participate in the review and evaluation of first-of-a-kind digital health technology and participate in precedent-setting research.
- Identify opportunities in creating preconditions and incentives informing digital health policy proposals, meeting CDRH's mission to protect and promote public health while supporting technological advances.
- Provide advice, consultations and training to internal and external experts on current state of digital health technologies, policies, and functionalities.
- Assist with identifying and evaluating technology solutions that will enhance internal processes for FDA's Center for Devices and Radiological Health.

What is FDA looking for in candidates?

- Comfortable in a fast-paced, customer-oriented, and flexible environment.
- A bias toward action and a proven track record of delivering projects and products.
- Have excellent communication skills to engage an organization of multiple specialties.
- Ability to actively seek out multiple opinions, yet make independent decisions and influence positive outcomes.
- Have practical experience and technical expertise focusing on one or more areas of digital health, including:
 - o Mobile medical apps, medical device interoperability, and healthcare cybersecurity
 - o Digital therapeutics, machine learning, artificial intelligence and novel digital health technology
 - o Digital health product development, software as a medical device
 - o Big data and advanced analytics, cloud storage and computing and wireless communication



Position information:

Location: Silver Spring, Maryland (White Oak Campus)

Application Period: Tuesday October 20, 2020 through Tuesday November 20, 2020

Salary: Salary is commensurate with education and experience

Telework Eligible: Yes, as determined by supervisor

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. <u>Additional information on 21st Century Cures Act can be found here.</u>

This is a confidential filing position. As such, this position is subject to FDA's prohibited financial interest regulation and may require the incumbent of this position to divest of certain financial interests. If selected, the employee must complete FDA's ethics preclearance requirements and file a financial disclosure report (OGE-450) prior to receiving an official offer of employment.

Benefits:

A career with the U.S. Government provides employees with a comprehensive benefits package. As a federal employee, you and your family will have access to a range of benefits that are designed to make your federal career very rewarding. Learn more about federal benefits: Working in Government-Benefits.

Conditions of Employment:

- One-year probationary period may be required.
- Background and/or Security investigation required.
- U.S. citizenship is required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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.

Background Investigation Requirement:

All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later date.

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.

Why is FDA a great place to work?

FDA offers great employee benefits, and we promote healthy work/life balance with flexible scheduling and telework, and many on-campus amenities including a childcare center, a free fitness facility with a variety of classes, and more. FDA's location in Montgomery County, Maryland near Washington, D.C. offers great public schools, public transportation, and a wealth of cultural and recreational choices.

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 DigitalHealth@fda.hhs.gov, with "DHCoE Digital Health Advisor" in the subject line.



