



Job Title: Digital Health Specialist – Generative AI
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Digital Health Center of Excellence (DHCoE)
Division of Digital Health Technology Assessment (DDHTA)

Summary:

The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), [CDRH/DHCoE/DDHT](#) and being filled under FDA’s Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA’s ability to recruit and retain scientific, technical, and professional experts in certain occupational series that “support the development, review, and regulation of medical products.” The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

Become a part of the Department that touches the lives of every American.

At the [Department of Health and Human Services \(HHS\)](#) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Devices and Radiological Health ([CDRH](#)) is to protect and promote public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate 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 United States.

Title 21 Band D, GS-14/15 equivalent

[Overview](#)

Open & Closing Date: 10/21/2024 - 11/20/2024
Salary Range: \$139,395-\$219,045
Band: D
Occupational Series: 0301
Duty Location: Remote
Remote Job: Yes
Telework Eligible: No
Travel Required: Yes
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: D
Supervisory Status: No
Security Clearance: Public Trust/Moderate Risk
Drug Test: No
Position Designation: Moderate Risk
Trust Determination Process: Public Trust

This job is open to: Open to the Public

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Duties

The Digital Health Specialist bridges generative AI expertise, with the broader regulatory and strategic landscape of health care technology innovation. The Digital Health Specialist requires collaboration with regulatory experts, policymakers, and health care professionals to ensure that AI models used in medical devices meet the highest standards of safety, performance, and compliance with federal regulations. The Digital Health Specialist leads and contributes to complex and innovative projects as part of an agile team of experts within a fast-paced and technically demanding ecosystem.

The Digital Health Specialist supports public health through the development, review, and implementation of regulations, policies, procedures and guidances related to software and digital health. Serves as a technical and scientific consultant and advisor to the Division Director, Digital Health Technology Assessment 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, including generative artificial intelligence. The Digital Health Specialist uses various methods, processes, and techniques to support the development and delivery of public health or health-related programs.

As an expert in formal scientific principles and experience in Health IT, the incumbent provides information, advice, and consultation to government entities, federal agencies, private industry, and/or universities on unique and complex scientific or regulatory issues. Serves 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, machine learning and artificial intelligence including generative artificial intelligence. Exercises discretion, analytical skill, judgment and personal accountability and responsibility for developing research programs.

Provides scientific expertise as well as specialized analytical expertise on a wide variety of regulatory issues and matters. Establishes and maintains liaisons with medical device companies, professional organizations, industry associations/groups, patient advocacy groups, academia, and other federal and foreign agencies with mutual interest in digital health as it pertains to medical devices.

Analyzes and evaluates 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.). Presents, explains, and justifies recommended project/program management activities to senior CDRH and Digital Health Center of Excellence management. The incumbent provides medical device regulatory support for digital health issues.

Analyzes current and emerging business models related to digital health using input from investment community, industry, healthcare providers, patients, staff, and other stakeholders. Proactively identifies technology trends and evolving science that may influence digital health technologies, medical device development, evaluation, and regulatory policy. Develops and provides strategic direction related to software and digital health with various CDRH scientific and professional staff, investment community, industry, device manufacturers, healthcare providers, patients, staff, and other stakeholders, specifically in medical device community.

Prepares and/or delivers legislative testimony on consumer and regulatory, and policy analysis issues regarding digital health. Makes presentations at medical and scientific review panels, advisory committees, formal professional meetings at the national level, and before large

consumer groups. Leads the development and presentation of national and local training programs within the digital health arena.

Reviews, analyzes, and improves digital health policy proposals and related regulatory deliverables including how technical changes affect medical device product safety and public health. Identifies opportunities and barriers for the development of innovative medical devices incorporating digital health technologies and improving the processes both internal and external related to software and digital health that may affect regulatory/policy changes greatly. Coordinates with other subject matter experts on the development and dissemination of regulatory health policy. Communicates strategies related to software and digital health to include machine learning and artificial intelligence, including generative artificial intelligence with internal and external stakeholders.

Identifies opportunities for innovation and assess the healthcare marketplace for obstacles and technical hurdles to the business success of digital health technologies. Represents the Center within and outside FDA on projects pertaining to digital health program requirements. Identifies opportunities and risks for modifying CDRH's digital health approach to premarket review and post market surveillance of medical devices to promote timely, efficient scientific assessment and review of innovative products.

Makes significant technical contributions that advance the state-of-the-art technology used in Cyber-Physical Systems. Determines when major developments should be reconsidered, or major alterations should be made due to program changes. Partners with other government and industry experts to develop new concepts and approaches for Digital Health programs in the center.

Presents CDRH's policies to national organizations, government agencies, state and local governments, industry, academia, consumer organizations, Congress, and/or the scientific community.

Requirements

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.

- Males born after December 31, 1959, must be registered with the Selective Service. Please go to <http://www.sss.gov> for more information.
- One-year probationary period may be required.
- One-year supervisory probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- 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 time.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.

Qualifications

Minimum Years of Experience is the new standard, rather than specialized experience, for determining and validating a Title 21 candidate's band. This standard applies across all Title 21 positions.

Minimum Years of Experience required for Band D:

- Bachelor's – 5 Years
- Master's – 4 Years
- Doctorate and/ or JD – 3 Years
- No qualifying degree – 7 Years

In order to qualify for a **Digital Health Specialist, AD-0301** you must meet the following requirements:

Basic Qualification Requirements:

Education: A bachelor's degree or higher in a science, technology, engineering, mathematics, computer science, statistics, or software engineering. The degree must be from an accredited program or institution.

OR

Experience: Comparable work in digital health policy, digital health technology support, digital health training, medical device cybersecurity, artificial intelligence/machine learning, regulatory science advancement, regulatory review support and coordination, advanced

manufacturing, real world evidence and advanced clinical studies, regulatory innovation, or digital health strategic partnership.

In order to qualify for the **Digital Health Specialist** which falls under the **0301** Series, you must meet the following requirements by 11:59pm EST on **11/20/2024**.

Desired Professional Experience/Skills:

The ideal candidate will possess the following professional experience/skills:

- Experience performing work that provide regulatory evaluation, oversight, regulatory operations, and policy guidance in the field of public health by advancing Artificial Intelligence (AI), including generative Artificial Intelligence (genAI) and Machine Learning (ML). Using techniques that can include statistical modeling, algorithms, Natural Language Processing (NLP), and other forms of machine learning that create artificial intelligences. Also performing work to inform public health decision making or advance business and regulatory systems by applying statistical techniques and other forms of machine.
- Strong collaboration skills
- Effective stakeholder engagement
- Excellent problem solving and communication skills
- Adaptability in a highly agile environment
- Desire to drive for continual improvement at the personal, team, and organization level

Education

Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current employee, you are not exempt from transcript requirements.

TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. You must submit an official transcript, unofficial transcript, or a list including courses, grades earned, completion dates, and quarter and semester hours earned. **Transcripts must identify a degree type, date degree conferred, and identify the major if using education to meet basic degree requirements.**

Education must be accredited by an accrediting institution recognized by the [U.S. Department of Education](#) in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by the U.S. Department of Education.

If you are using education completed in foreign colleges or universities, see the [Foreign](#)

Education section below for additional requirements.

Electronic Transcript Caution: If you have obtained your transcripts electronically, the file might contain security measures that could prevent our application system from reading the file. Therefore, you should consider asking the institution to provide the file in a non-secured electronic format. Alternatively, you could scan or take a photo of the printed copy of the transcript. If your uploaded transcript cannot be read by our system, you may receive consideration and credit for the information we can access.

See the [Application Manager Documentation](#) for tips on submitting your paper-based documents.

Foreign Education: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. **For further information, visit the [U.S. Department of Education website for Foreign Education Evaluation](#).**

To be acceptable, the foreign credential evaluation must include/describe at a minimum, the following information: (1) The type of education received by the applicant; (2) The level of education in relation to the U.S. education system, and state that its comparability recommendations follow the general guidelines of the International Evaluation Standards Council; (3) The content of the applicant's educational program earned abroad, and the standard obtained; (4) The status of the awarding foreign school's recognition and legitimacy in its home country's education system; and (5) Any other information of interest such as what the evaluation service did to obtain this information, the qualifications of the evaluator, and any indications as to other problems such as forgery.

Note: Some positions require the completion of specific courses or a specified number of credit hours. Therefore, the foreign credential evaluation should provide information similar to that of an official transcript, to include a list of the courses taken, quarter and/or semester hours awarded, the cumulative grade point average (GPA), honors received, if any, date degree awarded.

Applicants can request an evaluation from a member organization of one of the two national associations of credential evaluation services listed below:

1. [National Association of Credential Evaluation Services](#) (NACES)
2. [Association of International Credentials Evaluators](#) (AICE)

Credential evaluations are not free, and applicants are responsible for the cost of the selected service.

For more information about this requirement, please visit the [U.S. Department of Education website for Foreign Education Evaluation](#).

Additional Conditions of Employment:

- **Pre-employment physical required:** No
- **Drug testing required:** No
- **License Required:** No
- **Mobility agreement required:** No
- **Immunization required:** No
- **Bargaining Unit:** 3591
- **Telework eligible position:** Telework is at the discretion of the supervisor.
- **Remote eligible position for highly qualified candidates at the discretion of the supervisor.**

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: <https://www.fda.gov/about-fda/jobs-and-training-fda/ethics>.

Additional Information:

- **Additional selections may be made for similar positions within the commuting area(s) of the locations listed through this vacancy announcement.**
- **If you are serving or have served in the last 5 years (from 12/01/2023) as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. See [Political Appointee FAQ - OPM](#) for more.

How to Apply

Submit resume or curriculum vitae, cover letter (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), SF50 (if applicable), a copy of your unofficial transcripts (if applicable), by **11/20/2024** to CDRHRecruitment@fda.hhs.gov. **Compile all applicant documents into one combined document (i.e., Adobe PDF)**. Candidate resumes may be shared with hiring official within the CDRH with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. Please include the following Job Reference ID in the subject line of your email submission: **CDRH/DHCoE/DDHTA Digital Health Specialist-Generative Artificial Intelligence**

PHS Commissioned Corps Officers interested in performing the duties of this position within the Commissioned Corps may apply to this announcement. Officers must follow the instructions for how to apply and include their most recent orders in addition to the required documents. If selected, candidates will be referred to (CC) personnel and not as candidates for a Cures appointment.

All requirements must be met by the closing date of this announcement 11/20/2024; only education and experience gained by this date will be considered. You must continue to meet all requirements throughout the entire hiring process.

How you will be Evaluated:

You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement. Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

If you are referred to the hiring manager for consideration, you may be further evaluated based on an interview; review of requested work samples, writing samples, most recent performance evaluation(s), or professional references; or results of an oral presentation or work-related test.

Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Please follow all instructions carefully. Errors or omissions may affect your eligibility.