



**Job Title: Chief Medical Officer (Associate Director)
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)
Office of Health Technology IV (OHT4)/ Office of Surgical and Infection Control Devices**

Summary:

The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Office of Product Evaluation and Quality (OPEQ), Office of Health Technology IV (OHT4) 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 or Center](#)) 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 AD-Band E, GS-15 equivalent

Minimum - \$195,000.00

Maximum - \$309,337.00

Salary: Salary is commensurate with education and experience and starts at \$195,000.00

Overview

Open & Closing Date: November 29, 2024 - December 30, 2024
Salary Range: \$195,000.00 to \$309,337.00
Band: E
Occupational Series: Physician (0602)
Duty Location: Remote
Remote Job: Yes
Telework Eligible: N/A
Travel Required: Requires up to 25% travel
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: E
Supervisory Status: No
Security Clearance: Public Trust/High Risk
Drug Test: No
Position Designation: High Risk
Trust Determination Process: Public Trust

This job is open to: Open to the Public

Hiring Path Clarification Text: 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

- Serves as the Chief Medical Officer (CMO) and as an Associate Director. In this capacity, the incumbent will serve as the Office’s senior clinical advisor and program manager regarding the total product lifecycle review of in-scope surgical medical devices, infection control products and personal protective equipment, and any associated clinical concerns.
- Serving as a recognized expert, the CMO will provide clinical consultation to the Office Director , staff, colleagues across the Center, as well as CDRH and Agency leadership.
- As the Associate Director, the incumbent will advise Office leadership on trends noted in the clinical, patient, and scientific communities, as well industry regarding significant

concerns and reported adverse event data related to general surgery, plastic and reconstructive surgery, and infection control medical devices and products regulated by the Center.

- As a recognized clinical and surgical expert, the incumbent will collaborate with colleagues across the Office, as well as Center and Agency leadership to develop guidance documents, policies, and standards regarding the regulatory oversight of clinical trials and the use of clinical outcome assessments in the evaluation of general surgery, plastic and reconstructive surgery, and infection control medical devices and products regulated by the Center.
- Serves as the clinical authority in reviewing and evaluating clinical, surgical, and research findings, scientific properties, analyses, laboratory and clinical behavior, and the impact of these factors and properties on the safety and effectiveness of in-scope medical devices and infection control products.
- Evaluates the effectiveness of existing research support in relation to the Office's programs requirements. As such, the incumbent will develop or modify research plans as required to meet Office needs and coordinate activities and actions in this area with the Office of Science Engineering and Laboratories (OSEL), the Office of Clinical Evidence and Analysis (OCEA), and the FDA's Oncology Center of Excellence (OCE).
- Serves as the Office focal and primary point of contact for medical device clinical and surgical issues and provides expert and authoritative advice, guidance, assistance, interpretations, consultations, and recommendations to Office staff , as well as Center and Agency officials.
- Drafts decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, manufacturing, and reliability concerns.
- Provides briefings and recommendations to senior and executive level Agency and Departmental officials.
- Proposes, writes, evaluates and explains product review and other medical guidelines or criteria concerning the data in applications submitted to the Agency for the review and approval of medical devices proposed for either investigational purposes or general marketing.

Requirements

Conditions of Employment

- U.S. Citizenship requirement 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.

Education and Professional Experience Qualifications:

In order to qualify for the Associate Director, which falls under the: Physician (0602), you must meet the following requirements by 11:59pm EST on **Monday, December 30, 2024**.

- A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent;
- **Degree from Foreign Medical School:** A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

AND

- **Graduate Training:** In addition to a degree, a candidate must have had at least one (1) year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US and Canada.

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

- Interpreting and assessing scientific data and technical reports to determine the safety and effectiveness of medical products;
- Familiarity with surgical procedures, clinical treatments, and medical device applications.
- Representing the organization on committees and at professional meetings, and conducting outreach to relevant stakeholder populations; and
- Reviewing and evaluating clinical and surgical research findings, scientific properties, analyses, laboratory and clinical behavior and impact on these factors.

How to Apply:

Submit resume or curriculum vitae, cover letter with a brief summary of accomplishments, SF-50 (if applicable) and a copy of unofficial transcripts in one document (Adobe PDF) to CDRHRecruitment@fda.hhs.gov, by **Monday, December 30, 2024**. Please include the following Job Reference ID in the subject line of your email submission: **Chief Medical Officer (Associate Director) - (OHT4/IO) – Last Name, First Name**

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.

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.

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: 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:** May be required
- **Bargaining Unit:** 8888
- **Telework eligible position:** This position is remote.
- **Incentives may be authorized:** No

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.

All requirements must be met by the closing date of this announcement **Monday, December 30, 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.