



**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 Health Technology I (OHT1)**  
**Division of Health Technology IA (OHT1A)**

**Application Period:** October 3, 2023 – November 7, 2023

**Area of Consideration:** United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

**Position:** Physician  
(Ophthalmologist – Glaucoma Specialist)

**Series:** [Physician 0602](#)

**Location(s):** Remote Eligible

**Salary:** Salary is commensurate with education and experience and starts at \$165,000.00.

**Work Schedule:** Full-Time

**Cures Band(s):** Band C

**Full Performance Band Level:** Band C

**Travel Requirements:** 25% travel or less

**Supervisory:** No

**Bargaining Unit:** 8888

**This position is being filled under a stream-lined 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 this authority.**

**Additional information on 21st Century Cures Act can be found here:**

[21st Century Cures Act Information](#)

## 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 are safe and effective.

The Center for Devices and Radiological Health ([CDRH or Center](#)) serves as the medical devices regulatory arm of the FDA and the Department of Health and Human Services ([HHS](#)). 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.

The Office of Product Evaluation and Quality ([OPEQ](#)) assures patients have access to high quality, safe, and effective medical devices and products throughout the total product lifecycle (TPLC) by implementing program areas through which medical devices are evaluated or cleared for clinical investigations and marketing. The Office of Health Technology I ([OHT1](#)), within OPEQ, is responsible for the TPLC review of ophthalmic, anesthesia, respiratory, ear, nose, and throat (ENT), and dental medical devices. This includes development and implementation of policies related to human subject protection, good clinical practice, and appropriate collection of real-world evidence (RWE).

## Duties/Responsibilities

The Physician (Ophthalmologist) reports directly to the OHT1/DHT1A (Division of Ophthalmic Devices) Assistant Director and serves as the clinical and technical expert in the field of Ophthalmology, specifically glaucoma. The Physician, Glaucoma Specialist, provides clinical, scientific, and technical leadership and expertise in policies and procedures with an emphasis on testing, evaluation, and quality control standards regarding ophthalmic medical devices, to include surgical instrumentation, ocular implants, and other products and diagnostic equipment used in the diagnosis and treatment of glaucoma.

- Serves as an authority on the latest developments in health care policy and the ophthalmic medical device industry. As such, conducts regulatory policy reviews related to the development aspects of medical devices, diagnostic equipment, and products used in the practice of Ophthalmology.
- Utilizes clinical expertise and technical knowledge to serve as an authoritative voice and principal advisor to the DHT1A Assistant Director and the OHT1 Office Director on matters regarding ophthalmic medical devices, diagnostic equipment, and products, encompassing the entire product lifecycle.
- Offers evidence-based recommendations regarding classification and petitions for the reclassification of new ophthalmic medical devices, as well as identifies areas where standards need to be developed.
- Develops guidelines for the study and development of ophthalmic medical devices and products classified in the premarket approval space.
- Provides guidance to industry to ensure approaches to research studies follow FDA regulatory protocols for novel and predicate ophthalmic medical devices and products.
- Evaluates proposed clinical trial protocol(s) for their ability to assess the safety, effectiveness, and reliability of new ophthalmic medical devices under development.
- Evaluates ophthalmic medical device clinical trial findings, risk to benefit data, scientific properties, safety data, and the overall impact of existing devices, as well as new technologies submitted to the Center.
- Supports review staff by sharing clinical expertise in the pre-market, compliance, and post-market surveillance spaces, as well as regulatory policy knowledge and interpretation.

- Reviews and assesses the safety implications from post-market surveillance data and adverse event reports and recommends appropriate regulatory courses of actions.
- Coordinates, carries out, and makes post-market compliance and quality determinations (e.g., Establishment Inspection Report, Regulatory Audit Reports, Recalls, Allegations of Regulatory Misconduct, Labeling, Enforcement Actions, etc.)
- Coordinates, carries out, and makes post market surveillance determinations (e.g., Medical Device Reports, Post Market Surveillance Studies, Safety Signals, etc.)

## Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
  - a. **Qualified** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the [OPM Qualification Standards](#) as a baseline for comparing experience levels and other candidate attributes for relevant positions.
  - b. **Outstanding** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the “desired” criteria will not be excluded from consideration for this position.*

### **Education Requirement:**

Candidates must possess the required occupational requirements to qualify. Please use the following link to determine the series qualifications: [Physician, 0602](#)

### **Desired Education Requirement:**

Our ideal candidate will have completed a residency in Ophthalmology. A Glaucoma fellowship is highly desired.

### **Professional Experience:**

Our ideal candidate will possess:

- Ability to collaborate with a multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with medical products (i.e., devices, biologicals, drugs, etc.).
- Skill in identifying challenges, gathering information, drawing conclusions, and recommending solutions to complex issues.
- Ability to interpret and assess scientific data and technical reports to determine the safety and effectiveness of medical products.
- Ability to provide scientific support for regulatory questions and decisions regarding

specific requests from medical device and health technology industries and other Federal agencies.

### **Desired Professional Experience:**

- Skillful in effectively interpreting and presenting complex information and concepts, in both written and oral formats.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.
- Ability to actively embrace diversity by actively promoting an inclusive workplace that maximizes the talents of each person.
- Ability to focus on objectives and results when considering the various alternatives to a decision.

## How to Apply

Submit resume **and** cover letter by **November 7, 2023**, to [CDRHRecruitment@fda.hhs.gov](mailto:CDRHRecruitment@fda.hhs.gov) Please adhere to the following submission protocol:

- 1. Cover letter and resume should be one combined PDF document.**
- 2. Please reference DHT1A-OHT1 Physician September 2023 in the subject line of your email submission.**

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”.

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.

## Educational Transcripts

**SUBMITTING YOUR TRANSCRIPTS:** Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. 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 FDA employee, you are not exempt from transcript requirements.

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

## Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- 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.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. 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.

## Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive with a Risk Level of Moderate

A background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

## Ethics Clearance Requirements

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>.

## Equal Employment Opportunity

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

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](#).

## E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

## Announcement Contact

For questions regarding this Cures position, please contact [CDRHRecruitment@fda.hhs.gov](mailto:CDRHRecruitment@fda.hhs.gov)

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*FDA is an equal opportunity employer.*

