Job Title: Deputy Office 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, Immediate Office (OHT4/IO)

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 U.S. 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 Radiologocal 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 F
Minimum - $181,551
Maximum - $260,823
Salary: Salary is commensurate with education and experience and starts at $181,551

Overview

Open & Closing Date: Monday, September 30, 2024, through Tuesday, October 29, 2024
Salary Range: $181,551 - $260,000
Band: F
Occupational Series: Biologist (0401); Microbiologist (0403); Toxicologist (0415); General Health and Science (0601); Physician (0602); Regulatory Specialist (0696); General Engineer (0801); Materials Engineer (0806); Mechanical Engineer (0830); Electrical Engineer (0850); Electronics Engineer (0855); Biomedical Engineer (0858); Chemist (1320)
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: Band F
Supervisory Status: Yes - One Year Supervisory Probationary Period May be Required.
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. 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 DHT4 Deputy Office Director reporting to the OHT4 Office Director, providing assistant to the Office Director and a technical authority on devices with regard to safety and effectiveness, and senior advice and leadership to scientific, clinical, professional, and technical staff throughout the Office.
- The Deputy Office Director will also serve as the technical authority and principal advisor to the Office Director on the total product lifecycle of devices including premarket evaluation, compliance and quality, and surveillance programs.
- Engages regularly with internal stakeholders and external stakeholders such as the medical device industry, trade associations, other Federal agencies, other countries, State agencies, and the general public.
- Oversees medical device reviews and the decision-making process on classifications, petitions, 510(k)s, HDEs, PMAs, PDPs, De Novos, 513(g)s, IDEs, and all supplements and amendments to these submissions.
- Provides technical and non-technical leadership to device advisory panels and panel members and consultants and provides guidance on classification actions, petitions, 510(k)s, PMAs, PDPs, De Novos, 513(g)s and IDEs with Center and Agency components or other organizations.
- Oversees medical and healthcare compliance activities including inspection. classification, recall classification, labeling review, import alerts, custom device reports and surveillance activities including MDR review and analysis, 522 Studies, PAS studies.
- Makes decisions of national and international significance, which impacts the availability of and the safety and effectiveness of various medical device products.
- Provides information and consultation to individuals, federal agencies, private industries (medical device), universities, and/or foreign governments on scientific and public health issues.
- Represents the FDA/CDRH at national scientific conferences, multiple stakeholder committees, registry steering committees, national working groups, and/or FDA advisory panel meetings.

Supervisory Responsibilities: Direct a multi-disciplinary program, providing leadership and management oversight to subordinate support staff and division directors in the absence of, and in accordance with the Office Director. Plans, assigns, oversees, and directs the work to be accomplished, ensuring timely performance of a satisfactory amount and quality of work; sets and adjusts priorities and timeframes for completion of the work; provides advice and guidance to staff members; reviews work products and accepts, amends or rejects work; develops performance standards and serves as rating official on employee evaluations. Gives advice, counsel, or instruction to employees on both work and administrative matters. Interviews candidates for positions in the Division; recommends appointment, promotion or reassignment of such positions; hears and resolves complaints from employees, referring group grievances and more serious unresolved complaints to a higher-level supervisor or manager; effects minor disciplinary measures, such as warnings and reprimands, recommending other action in more serious cases; identifies developmental and training needs of employees; providing or arranging

for needed development and training, finds way to improve productivity or increase the quality of work directed; develops performance standards.

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.
- 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.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federalsalary 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.
- Must verify U.S. Citizenship in application email. Self-Declaration is acceptable.

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 F:

- Bachelor's – 7 Years
- Master's – 6 Years
- Doctorate and/ or JD – 4 Years
- No qualifying degree – 11 Years

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:

- Experience in pre-market device reviews.
- Advising, training, and guiding a multi-disciplinary staff responsible for medical, clinical, public health and/or regulatory activities associated with medical products (i.e., devices, biologicals, drugs, etc.).
- Leadership and management experience to provide technical and administrative leadership and direction in alignment with the Office Director to the Office through subordinate supervisors and exercises the full range of first and second-level supervisory responsibilities and oversight to subordinate support staff and Division Directors.
- Expertise in interpreting and presenting complex scientific, medical, clinical, and regulatory information and concepts, in both written and oral formats for a variety of audiences.
- Ability to identify key clinical and medical considerations related to medical devices; professional knowledge and understanding of current FDA regulations, policies, and procedures pertaining to safe and effective medical devices.
- Experience building collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.

Basic Qualifications:
Candidates must also possess the required individual occupational and educational requirements to qualify for this position. Please use the following links to determine the series for which you qualify: Biologist (0401); Microbiologist (0403); Toxicologist (0415); General Health and Science (0601); Physician (0602); Regulatory Specialist (0696); General Engineer (0801); Materials Engineer (0806); Mechanical Engineer (0830); Electrical Engineer (0850); Electronics Engineer (0855); Biomedical Engineer (0858); Chemist (1320)

How to Apply

Submit resume or curriculum vitae, unofficial transcripts, and a cover letter by ***Tuesday, October 29, 2024,*** to CDRHRecruitment@fda.hhs.gov. Compile the above mentioned applicant documents into **one** combined document (i.e., Adobe PDF). Additionally, candidates must verify U.S. Citizenship in the application e-mail. Self-declaration is acceptable. 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 their resume with "do not share". Please include the following Job Reference ID in the subject line of your email submission: ***Deputy Office 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.

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.

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 Authorized:** No
- **Financial disclosure statement, OGE-450, required:** Please be advised that this position may be subject to FDA's prohibited financial interest regulation and may require the incumbent of this position to divest of certain financial interests. Applicants are advised to seek additional information on this requirement from the hiring official before accepting this position.

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:

- **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 Tuesday, October 29, 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.

Announcement Contact
For questions regarding this Cures position, please contact CDRHRecruitment@fda.hhs.gov.

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