Job Title: Biocompatibility Expert (Interdisciplinary Scientist/ Engineer)
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)
Immediate Office (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), Immediate Office (IO), and is 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 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 - $163,964.00
Maximum - $225,011.00
Salary: Salary is commensurate with education and experience and starts at $163,964.00

Overview

Open & Closing Date: December 17, 2024 – January 16, 2025
Salary Range: $163,964.00 - $225,011.00
Band: E
Occupational Series: Biologist (0401); Microbiologist (0403); Pharmacologist (0405); Toxicologist (0415); General Health and Science (0601); Regulatory Specialist (0696); General Engineer (0801); Materials Engineer (0806); Mechanical Engineer (0830); Electrical Engineer (0850); Biomedical Engineer (0858); and 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: E
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: U.S. Citizens.

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

Reporting directly to an OPEQ Super-Office Director, this position serves as OPEQ's Biocompatibility Expert and the point-of-contact, authority, and leader for the analysis, development, and implementation of policies, procedures, guidance, and regulations specifically related to the oversight of biocompatibility reviews for device evaluation programs activities. As the top expert, the incumbent provides information and consultation to individuals, federal

agencies, private industry, universities, and/or foreign governments on biocompatibility issues. In doing so, the incumbent:

- Evaluates device biocompatibility and assesses biological risks, especially to avoid adverse reactions. The incumbent scientifically reviews and analyzes safety data to provide recommended guidelines and policy analyses for devices considering the regulatory implications of such reviews and analyses.
- Writes and establishes policies and procedures that ensure the sufficiency and procedural adequacy of policy statements and policy initiatives. Interprets and applies existing policy, setting precedents that affect internal and industry program activities and the marketing of regulated products, specifically focusing on ensuring the consistency in biocompatibility policies, procedures, guidance and/or regulations.
- Prepares replies to correspondence from the regulated community and other interested persons on issues that are industry-wide in scope or have broad health implications and that concern precedent setting interpretations of FDA policy related to biocompatibility.
- Coordinates and leads Biocompatibility discussions with Medical Device Innovation Consortium (MDIC).
- Leads development of chemistry proposals for discussions with external parties (e.g., professional societies and trade associations).
- Ensures scientific standards ballot reviews are consistent with CDRH regulatory and scientific biocompatibility policy.
- Leads development of review aids and training to facilitate review consistency (e.g., chemistry review templates and training) and adherence to CDRH regulatory and scientific biocompatibility policy.
- Oversees development of programmatic changes in OPEQ biocompatibility programs and is responsible for coordinating with OPEQ Sub-office Leadership and SMEs to ensure appropriate implementation of programmatic changes.
- Serves as a liaison for biocompatibility reviews on behalf of the OPEQ programs and activities with other Offices, as well as serves as a biocompatibility device evaluation liaison for cross-Office policy programs and those led by other Offices, other government agencies, standard development organizations (SDOs) or stakeholders (e.g., industry, consumer groups). Identifies and ensures the participation of subject matter experts, e.g., engineers, scientists, medical officers, etc. (expertise in working with medical devices) on a variety of OPEQ programs and policies, specifically focusing on biocompatibility policies, procedures, guidance and/or regulations.
- Recommends long-range program plans, goals, objectives, and milestones, which serve as the basis for substantive changes in the organization and administration of programs affecting large numbers of people. Advises OPEQ senior management of issues impacting the Offices and initiates solutions, strategies, or policy development.
- Researches and analyzes unstable or complex regulatory policy issues and based on conditions and factors, determines what information is required and collects data from many sources to determine whether additional training or corrective actions are necessary, specifically related to biocompatibility.
- Serves as expert authority in OPEQ Immediate Office for biocompatibility review issues that may arise in Appeals or other similar scenarios requiring OPEQ IO input.

- Serves as a principal advisor for the analysis, development and implementation of policies, procedures, guidance, and regulations specifically related to the oversight of biocompatibility review issues for device evaluation programs and activities. Provides advice on the interpretations of the laws, regulations, and policies applicable to the Center and FDA.

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.
- 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** verify U.S. Citizenship in their application e-mail. 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 E:

- Bachelor's – 6
- Master's – 5 Years
- Doctorate and/ or JD – 3 Years
- No qualifying degree – 9 Years

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); Pharmacologist (0405); Toxicologist (0415); General Health and Science (0601); Regulatory Specialist (0696); General Engineer (0801); Materials Engineer (0806); Mechanical Engineer (0830); Electrical Engineer (0850); Biomedical Engineer (0858); and Chemist (1320). These requirements, in addition to the years of experience requirements for Title 21, listed above, must be met by **January 16, 2025**, at11:59 PM EST.

How to Apply

Submit your resume or curriculum vitae, unofficial transcripts, and a cover letter by ***January 16, 2025,*** 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: ***OPEQ IO Biocompatibility Expert– 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: *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**: N/A
- **Incentives may be authorized:** No

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.*

All requirements must be met by the closing date of this announcement January 16, 2025; 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.

FDA is an equal opportunity employer.