

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 Science and Engineering Laboratories (OSEL)
Division of Biomedical Physics (DBP)

Position: OSEL/DBP Assistant Director (Supervisory Interdisciplinary Scientist)

Series: Biologist (0401), Pharmacologist (0405), General Health Scientist / Epidemiologist (0601), General Engineer (0801), Material Engineer (0806), Mechanical Engineer (0830), Electrical Engineer (0850), Biomedical Engineer (0858), General Physical Science (1301), Physicist (1310), Chemist (1320), Mathematical Statistics (1529). Statistics (1530),

Location(s): Silver Spring, Maryland

Travel Requirements: This position may require occasional travel up to 25%.

Application Period: March 23, 2021 through April 6, 2021

Salary: Salary starts at \$121,316 and is commensurate with education and experience.

Conditions of Employment: United States Citizenship is required.

Special Notes: This position is being filled under an excepted 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 the authority. <u>Additional information on 21st Century Cures Act can be found here.</u>

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 safe, and effective.

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. Within CDRH, the Office of Science and Engineering Laboratories (OSEL) is responsible for accelerating patient access to innovative, safe, and effective medical devices through best-in-the-world regulatory science. The Division of Biomedical Physics (DBP) contributes to this mission by conducting research and engineering studies in the areas of optical technologies, electrophysiology, functional monitoring, functional performance, electrical simulation, electromagnetics, and wireless technologies. The Division studies and evaluates medical devices and electronic products in support of product approval, product testing, enforcement, and standards development activities. To learn more

please visit the OSEL and DBP web pages for additional information.

Position Summary:

The successful candidate will assist the Division Director in driving the FDA mission by leading a team of scientist and engineers in their efforts to advance regulatory science on the biophysical interactions between medical devices and the human body. The Division focuses on issues related to, but not limited to: Advanced Patient Monitoring and Control; AR/VR – Extended Reality (XR)

Artificial Intelligence (AI)/ Machine Learning, Cardiovascular; Cardiovascular; Credibility Assessment in Modeling; Digital Pathology; Orthopedics, etc. The Assistant Director provides technical and scientific leadership to a diverse staff in varied technical disciplines. For this position, experience in one of the following fields is preferred: Magnetic resonance imaging (MRI), Patient monitoring and control, or Modelling. The Assistant Director's decisions have national significance that impact the availability of safe and effective medical devices and thereby affect the quality of health care available to the entire American population. Successful execution of this position will require demonstrated experience in strategic management and the ability to make difficult decisions.

Supervisory Responsibilities:

Provides leadership and management oversight to scientific, professional, and technical support staff. Supervises and evaluates staff who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision to subordinate staff performing the work and functions of the organizational unit. Obtains and identifies strategic objectives for the organization.

Duties/Responsibilities:

The Assistant Director performs the following:

- Provide technical and scientific consultation to division, office, Center and other high-level officials on program status, plans, trends and significant problems.
- As an international expert, lead active research in an area of science or engineering aligned with OSEL's mission (approximately 30 percent of the time).
- Lead the identification, analysis, consultation, and reporting on scientific, theoretical, and factual data, conditions, and problems related to assigned devices.
- Consult with medical, engineering and scientific experts in assigned device areas regarding the regulation of medical devices.
- Performs, leads, assigns and ensures quality of consult reviews for direct reports.

Professional Experience/Key Requirements:

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

- Skilled in leading the strategic achievement of organizational goals, evaluating and improving organizational performance
- Demonstrated management experience in implementing, participating in and evaluating the results of programs, projects, and managing related resources, personnel and activities.
- Ability to lead stakeholder outreach and educational programs in the area of

- biomedical physics.
- Skilled in developing and validating laboratory test platforms, measurement methods, instrument calibration capabilities, computational models, clinical endpoints and analytical procedures to characterize and evaluate devices and products.
- Ability to conduct focused scientific research related to laboratory science studies, engineering studies, laboratory science studies, and/or clinical studies.

Desirable Qualifications/Experience:

- Ability to identify, analyze, advise, consult, and report on scientific, theoretical, and factual data, conditions, and problems
- Ability to coordinate high-level interactions with officials in other organizational units.
- Ability to lead and communicate a vision of excellence for others that motivates them to improve.
- Ability to work collaboratively with a diverse cadre of customers and stakeholders.
- Ability to prioritize and make critical decisions

Basic Qualifications:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Additional Conditions of Employment:

- One-year probationary period may be required.
- Background and/or Security investigation required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the <u>Selective Service System</u> OR have an approved exemption.
- This position may be subject to strict prohibited financial interest regulations which
 could restrict the type of financial interest (stock holdings) for the employee, the
 spouse, and minor children of the employee. For additional information on the
 prohibited financial interests, please visit the FDA Ethics and Integrity Office website
 at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply:

Prior to applying, please see the following instructions:

- Documents to submit: electronic resume or curriculum vitae, transcripts, and a cover letter containing a brief summary of accomplishments related to the position.
- Compile all applicant documents into one combined document (i.e. Adobe PDF)
- Include Job Reference code "2020-OSEL-DBP-010" in the email subject line.
- Email comprehensive applicant package/document to CDRHRecruitment@fda.hhs.gov by Friday April 6, 2021.

Equal Employment Opportunity Policy

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 Policy

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 <u>disability employment and reasonable accommodations</u> or <u>how to contact an agency.</u>

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

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