TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of New Drugs (OND)
Division of Pharmacology and Toxicology

Position: Interdisciplinary Scientist, Senior Advisor

Pay Plan-Series: AD-0401/0405/0415

Location(s): Silver Spring, MD

Travel Requirements: 25% or less

Application Period: 1/25/21-2/24/21

Salary: Starting at $142,701 (CURES Band E)

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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 compensated under the provisions of the authority. Additional information on 21st Century Cures Act can be found here.

Introduction:

The Food and Drug Administration (FDA) 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 mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter (OTC) and prescription

drugs, including biological therapeutics and generic drugs.

The Office of New Drugs (OND) is a dynamic, purpose-driven organization dedicated to the review of new drug applications, interactions with the pharmaceutical industry and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multi-disciplinary organization engaged in the oversight of human drug trials in the United States, in review of new drug applications (NDAs) and biologics license applications (BLA) for marketing drugs and therapeutic biologics in this country, and in regulating OTC drug products.

OND is looking for individuals with a commitment to scientific excellence and innovative thinking to support a dynamic and diverse organization. OND is conducting a search for talented individuals for the position of Interdisciplinary Scientist, Senior Advisor in the Office of New Drugs, Immediate Office, Pharmacology and Toxicology Staff.

Position Summary:

The **Interdisciplinary Scientist (IDS)** serves as a senior advisor to the OND Non-Clinical Director and is responsible for establishing policies, practices, processes, guidance development, and facilitating research in microphysiological systems (MPS). The recent advent of MPS – microfluidic biomimetic devices that aspire to emulate the biology of human tissues, organs and circulation in vitro – is envisaged to enable a global paradigm shift in drug development.

Supervisory Responsibilities: N/A

Duties/Responsibilities:

- Identifies gaps or opportunities in nonclinical development of medicinal products, conceives approaches for MPS during drug development and leads an office-wide taskforce or working group to address the potential role in drug development. The impact of the responsibilities involves representation of OND nonclinical needs to various internal and external stakeholders promoting contextual, regulatory use of New Alternative Methodology (NAM)/MPS drug development.
- Discusses FDA-wide new in vitro, in vivo, and in silico methods, including research, training, and communication with OND leadership and nonclinical review staff as it relates to MPS. Engage with U.S. Federal partners and global partners (e.g. FDA Office of Chief Scientist, CDER Center Director, Center for Food Safety and Applied Nutrition (CFSAN)), International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), drug regulatory agencies to promote discussion, development, and acceptance of regulatory performance criteria for such assays.
- Establishes dialogue and develops partnerships with internal and external OND stakeholders to explore regulatory science applications for MPS technologies and their contextual use. Identifies the performance criteria of MPS by engaging with FDA experts and FDA stakeholders through public-private partnerships.

- Publishes performance criteria results or initiates guidance development based on the results and presents the overview and outcomes at relevant internal and external meetings as related to MPS.
- Participates in the development and implementation of new OND-level nonclinical policies and practices related to MPS. Serves as a member of the OND Nonclinical Senior Leadership Team. Collaborates with nonclinical Division leadership within OND to improve the quality and consistency of activities carried out by the nonclinical discipline (i.e. drug and biologic review activities). Works as a member of a team with other Senior Leadership staff toward the development and implementation of standards of excellence in nonclinical evaluations designed to enhance the nonclinical toxicology programs of OND and the Center. Makes authoritative recommendations that become accepted for implementation as OND procedures.
- Serves as the OND representative on working groups or coordinating committees as called upon by the OND Nonclinical Director to consider problems or directions within the nonclinical discipline with new alternative methodologies. Develops proposals for study based on the mission and speaks on behalf of OND on nonclinical discipline matters as designated. Evaluates all types of new alternative methodologies final work products and evaluates their application for OND.
- Participates in outreach programs and engage stakeholders and patient advocates in critical discussions to improve nonclinical product development for a patient-focused drug development. Actively participates in professional meetings and addresses stakeholders involved in cross-cutting nonclinical aspects of product development related to MPS.
- Represents OND, as appropriate, in the development of internationally harmonized guidance documents for the safety assessment of medicinal products, such as guidance developed by the ICH as relates to MPS.
- Participates in conceiving OND-level workshops and symposia to review the state of the science and discusses opportunities to develop better nonclinical approaches for activity or safety assessment of products regulated by CDER. Participates in establishing methodologies and guidelines based on these discussions and continually appraises the quality of newly implemented approaches related to MPS.

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. Click here to find out additional information about the 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 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.

Click here to learn more about disability employment and reasonable accommodations or how to contact an agency.

Professional Experience/Desirable Qualifications:

The IDS works closely with a Clinical Division specializing in specific therapeutic areas, and thus should have research or work experience in the corresponding disease areas.. The IDS is a scientist with a background in a relevant field that includes biology, immunology, pharmacology, physiology, chemistry/ biochemistry, toxicology, or pathology and serves as the technical authority on scientific, regulatory decisions as related to the nonclinical evaluation of the medicinal products under review in accordance with OND regulatory guidance.

Competitive candidates will have earned a doctoral degree in one of the following:

General Natural Resources Management and Biological Sciences Series, 0401

Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

Or

Combination of education and experience: Courses equivalent to a major plus appropriate experience or additional education.

Pharmacology Series, 0405

Degree: major in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology.

Toxicology Series, 0415

Degree: toxicology; or an appropriate discipline of the biological, medical, or veterinary sciences that included at least 30 semester hours in chemistry, biochemistry, or physiology, and 12 semester hours in toxicology.

Specialized Experience

- Expertise with the integration of in silico computational approaches with in vitro toxicology and in vivo reference data for hazard identification and risk characterization
- Demonstrated experience in Quantitative Structure Activity Relationships (QSAR), data mining, virtual screening, chemogenomics, ADME-Tox, or combinatorial chemistry
- Ability to foster effective scientific collaborations across groups from different disciplines
- Possession of data science and computational skills or equivalent languages or software

Conditions of Employment:

1. **Security Clearance:**

This position requires a Public Trust security clearance and the incumbent has access to sensitive, proprietary, or financial information.

2. **Ethics Requirements**:

This position is 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. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. 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.

3. How to Apply:

Please submit resume or curriculum vitae with cover letter **by February 24, 2021** to ONDIORecruitment@fda.hhs.gov. Candidate resumes may be shared with the hiring official in CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share." For questions, please contact ONDIORecruitment@fda.hhs.gov. Please reference Job Code: OND-DPT-100 in the subject line of your submission.

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