Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Veterinary Medicine (CVM)
Office of the Center Director
Associate Director, Animal Bioengineering and Cellular Therapies

Application Period: 2/15/23- 03/17/23

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: Associate Director, Animal Bioengineering and Cellular Therapies

Series: 0601 General Medical and Healthcare Series

Location: Remote Eligible

Salary: Salary is commensurate with education and experience starting at $177,123 - $254,461

Work Schedule: Full Time

Full Performance Band Level: Band F

Cures Band: Band F

Travel Requirements: Up to 10%

Bargaining Unit: 8888

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

This position is being filled under a streamlined 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 meet applicable standards. The mission of the Center for Veterinary Medicine (CVM) is to protect the public health of the nation through its regulation of veterinary drugs, feed additives, animal devices and animal biotechnology

products. CVM's regulatory functions are geared to ensure that products subject to FDA regulation meet the applicable statutory standards, are safe (and, as applicable, effective), properly manufactured, and accurately and informatively labeled.

Duties/Responsibilities: As the Associate Director, Animal Bioengineering and Cellular Therapies in CVM/Office of the Center Director, you will:

A. Lead CVM's efforts in continuing to implement its regulatory approach to animal biotechnology and cellular therapy products.

B. Provide scientific and strategic direction for a smart regulatory approach to bring innovative biotechnology and cellular therapies to market to address unmet needs related to agricultural resilience, animal health, and veterinary medicine.

C. Strengthen CVM's efforts to conduct and increase outreach and education to developers, industry, and other interested stakeholders to guide them through the regulatory process.

D. Serve as an authoritative expert and resource to facilitate the application of quality regulatory science and science policy for the review and regulation of animal biotechnology and cellular therapy products.

E. Serve as an expert and resource to facilitate the discussion and resolution of complex regulatory science and science policy questions relevant to the review and regulation of animal biotechnology and cellular therapy products.

F. Provide guidance and formal communication clearance decisions, drawing on an in-depth and authoritative understanding of current regulatory science, science policy and regulation, to CVM staff for external communications related to animal biotechnology and cellular therapies.

Supervisory Responsibilities:

Organizational Management: Serves as the scientific expert and provide international programmatic support for the review of studies submitted in support of the evaluation of animal biotechnology and cellular therapy products.

Program Management: Oversees and coordinates activities in support of the Center and Agency strategic plans. Reports progress and challenges to the Center Leadership Team to ensure achieving the project goals.

Resource Management: Consolidates and balances resource needs of multiple projects relevant to the application of regulatory science to the review and evaluation of animal biotechnology and cellular therapy products.

Personnel Performance Management: Counsels and rates immediate subordinates.

Human Capital Management: Identifies ways to meet employee competency goals.

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.
- One year supervisory probationary period may be required.
- 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.

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:

Degree: Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained. For more information, please see: OPM Occupational Series Qualification Requirements.

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: OPM Occupational Series Qualification Requirements.

Desired Education:
Competitive candidates will have earned a doctoral degree in the relevant life sciences or Doctor of Veterinary Medicine or equivalent. Advanced certification in relevant scientific disciplines is encouraged.

Professional Experience:

- Recognized scientific expert in animal biotechnology and cellular therapies.
- Familiarity with regulating products under the Federal Food, Drug, and Cosmetics Act.
- Engaging with internal and external stakeholders in scientific inquiry.

Desired Professional Experience:

- Priority will be placed on candidates with relevant and recent experience in FDA or another regulatory federal agency, and an understanding of the laws and regulations pertinent to FDA.
- Priority will be placed on candidates with an understanding of and experience in laboratory research and application of the scientific methods.

Education 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.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements:

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.

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

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:

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.

How to Apply

Please submit your letter of interest, resume, and copy of transcripts by 03/17/23 to: CVMOpportunities@fda.hhs.gov with the subject line of "Title 21 Associate Director, Animal Bioengineering and Cellular Therapies – CVM."

Announcement Contact:

For questions regarding this Cures position, please contact CVMOpportunities@fda.hhs.gov using the subject line provided above.

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FDA is an equal opportunity employer.