

Opportunity Title: FDA Postdoctoral Fellowship in Immunogenicity of Adeno

Associated Viral (AAV) vectors in Gene Therapy

Opportunity Reference Code: FDA-CBER-2022-16

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CBER-2022-16

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A complete application consists of:

- An application
- Transcripts – [Click here for detailed information about acceptable transcripts](#)
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- A cover letter (upload in Writing Sample area)
- Three educational or professional recommendations

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CBER@oraui.org. Please include the reference code for this opportunity in your email.

Description ***Applications will be reviewed on a rolling-basis, and this posting will remain open until filled.**

A research opportunity is currently available in the Office of Tissues and Advanced Therapies (OTAT) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

AAV is a small viral vector commonly used for gene delivery. AAV based gene therapies are beginning to show clinical successes. However, due to the viral origin of AAV, there is a growing body of evidence demonstrating interactions of AAV vectors with the innate and adaptive immune system which hinder their successful translation from the bench to the bedside.

Our lab's goal is to develop technologies to help evaluate and mitigate the adaptive immunogenicity of AAV vectors in gene therapy. The selected participant will help to rationally design next generation AAV vectors with lower immunogenicity and test the efficacy of these designs in mice models. The fellow will conduct research in a highly translational and collaborative environment and learn techniques including AAV production and quantification, cloning, mutagenesis, screening techniques and humoral and cellular immunological assays.

Anticipated Appointment Start Date: March 2022; start date is flexible

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for five months, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation



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only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.





FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The qualified candidate should have received a doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred skills:

- Experience in the purification and characterization of proteins in mammalian systems. Preferably, experience in production and purification of viral vectors.
- Recombinant DNA techniques
- Excellent tissue culture techniques
- Experience with computational HLA binding, structural biology and protein design
- Immunological assays including flow cytometry, measuring T-cell mediated immune responses, ELISpot, ADA, Nab and ELISA
- Animal models
- Willingness to learn new technologies and methods

- Eligibility Requirements**
- **Degree:** Doctoral Degree received within the last 60 month(s).
 - **Discipline(s):**
 - **Chemistry and Materials Sciences** ([12](#) )
 - **Engineering** ([27](#) )
 - **Life Health and Medical Sciences** ([48](#) )
 - **Science & Engineering-related** ([1](#) )

Affirmation Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)