

Opportunity Title: FDA Chemical Synthesis of Nucleic Acid-Based Drugs

Fellowship

Opportunity Reference Code: FDA-CDER-2019-0422

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

Reference Code FDA-CDER-2019-0422

How to Apply 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
- One educational or professional recommendation. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

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

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

Application Deadline 12/31/2019 3:00:00 PM Eastern Time Zone

Description A research opportunity is available in the Office of Pharmaceutical Quality/Office of Biotechnology Products, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project in the Office of Pharmaceutical Quality (OPQ), Office of Biotechnology Products (OBP) will address the critical issue associated with the delivery of miRNA sequences to cancer cells. This may require the conjugation of miRNAs to gold nanoparticles or to other well established delivery reagents.

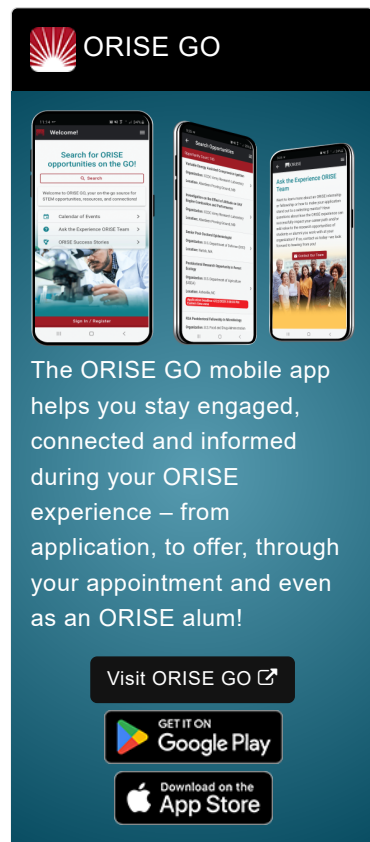
Under the guidance of a mentor the participant will be trained on:

- designing iminooxymethyl pyruvates as potential 2'-hydroxyl protecting groups for ribonucleosides based on the decarboxylative properties of alpha-oxyimino acids
- synthesizing ribonucleosides with 2'-iminooxymethyl pyruvate protecting groups and synthesizing RNA sequences using solid-phase techniques
- demonstrating that the decarboxylative removal of the new 2' -hydroxyl and nucleobase protecting groups improved the deprotection kinetics and purity of synthetic RNA sequences
- developing a method for the conjugation of RNA sequences to gold nanoparticles or to other well established delivery reagents through a thermolytic linker.

This training will prepare the participant for a successful career transition into regulatory science research, specifically, understanding the safety and efficacy of synthetic DNA and RNA sequences for the diagnosis and treatment of human diseases.

***Although the application deadline is December 31, applications will be reviewed on a rolling-basis.**

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 one year, 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



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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 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, with an emphasis on nucleoside synthesis. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Familiarity with laboratory techniques used for the purification and characterization of nucleosides; to include chromatography on silica gel, reversed-phase and ion-exchange HPLC-based methods
- Familiarity with product characterization techniques including UV/VIS, NMR spectroscopies (¹H, ¹³C and ³¹P) and mass spectrometry
- Evidence of scientific productivity based on scientific articles (3 preferred) published in peer-reviewed journals

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
 - **Chemistry and Materials Sciences** ([3](#) )