Opportunity Title: FDA Research Opportunity in Nuclear Magnetic Resonance
Opportunity Reference Code: FDA-ORA-2019-0003

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

Reference Code FDA-ORA-2019-0003

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, unless 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.OC.other@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 6/17/2019 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

A research opportunity is currently available with the U.S. Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Northeast Regional Laboratory (NRL) located in Jamaica, New York.

The fellowship is within the Northeast Regional Laboratory Facility where the following analytical techniques will be used to support critical regulatory testing and research activities: High Performance Liquid Chromatography (HPLC, UPLC), Size Exclusion Chromatography (SEC), Liquid Chromatography Mass Spectrometry (LC/MS/MS), Ion Exchange Chromatography, Spectroscopy (FTIR, UV/VIS, fluorescence, XRF, Raman), high resolution mass spectrometry (HRMS), Polarized Light Microscopy capabilities and Nuclear Magnetic Resonance Spectrometer (NMR).

The Pharmaceutical Analytical Group has been developed in Northeast Regional Laboratory to support the regulatory needs of Office of Regulatory Science (ORS) and Center for Drug Evaluation (CDER) scientists in the area of evaluation of protein-based pharmaceuticals (nano-scale) for therapeutic safety and efficacy to safeguard patient health and wellness. This group is formed to support ORA in developing and executing NMR-based analytical methods to qualify complex drugs.

Under the guidance of a mentor, the participant will be performing NMR analyses of pharmaceutical products. In this process, they will be learning about regulatory testing, generating regulatory analytical packages that can withstand scrutiny, learning about analytical quality controls and gaining experience with regulatory laboratory processes such as maintaining sample chain of custody, preparing samples per program guidelines in a way to preserve the regulatory value of the sample. They will also learn about horizon scanning and being able to identify projects to support regulatory needs in pharmaceutical analysis area.

The FDA Northeast Regional Laboratory is located in the York College Campus of City University of New York in Jamaica, New York. This can be conveniently reached by New York City Subway and Long Island Rail Road (LIRR).

This program, administered by ORAU through its contract with the U.S. Department of Energy to

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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 Jamaica, New York, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

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, or be currently pursuing the degree and will reach completion by the start date of the appointment. Degree must have been received within five years of the appointment start date.

Close familiarity with NMR, NMR maintenance, preparing and running samples on the NMR, operating the instrument, and the ability to analyze and derive information from NMR spectra is preferred.

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 6/17/2019 12:00:00 AM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Life Health and Medical Sciences** (2 👁)