Opportunity Title: Multi-Disciplinary Research Fellowship - ORA/NRL
Opportunity Reference Code: FDA-ORA-NRL-2019-0001

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

Reference Code FDA-ORA-NRL-2019-0001

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
- Two educational or professional references

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

If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Description A postgraduate research opportunity is available at the Food and Drug Administration (FDA), at the Northeast Regional Laboratory, Jamaica, NY.

The fellowship is within the Northeast Regional Laboratory Facility where the following analytical techniques will be used to support the 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 the regulatory aspects of innovative drug products of the future.

The participant may have the opportunity to:

- Develop regulatory methods for pharmaceuticals which utilize emerging technologies (e.g. nanotechnology, biotechnology, etc.)
- Apply liquid chromatography/mass spectrometry techniques and the characterization of pharmaceuticals which utilize novel delivery mechanisms and/or protein components
- Research testing strategies for protein-based reference drugs, biosimilars and nano-scale pharmaceuticals to ascertain the purity, concentration, consistency and identity, ratio of free/bound forms, including product related impurities and process related impurities
- Investigate NMR in the study of protein based drug products

Desired start date for this appointment is November 1, 2018.

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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-ORA in the Jamaica, NY 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.

Qualifications

Applicants must have received a doctoral degree in chemistry, biochemistry, or physics with a strong emphasis in biochemistry within five years of the desired starting date, or completion of all requirements for the degree should be expected prior to the starting date. The candidate should have experience in the characterization of pharmaceuticals using spectroscopy, HPLC, LC/MS/MS, NMR or other currently published methodologies.

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Life Health and Medical Sciences** (1 👁)
  - **Physics** (1 👁)