

Opportunity Title: Northeast Regional Laboratory Fellowship - FDA ORA

Opportunity Reference Code: FDA-ORA-2016-0027

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

Reference Code FDA-ORA-2016-0027

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 postdoctoral research project training opportunity is currently available at the Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Northeast Regional Laboratory. The fellow will collaborate with multi-disciplinary research efforts within the Northeast Regional Laboratory Facility.

The fellowship is within the Northeast Regional Laboratory Facility where the following analytical techniques will be used to support these 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 fellow may gain experience by:

- Developing regulatory methods for pharmaceuticals which utilize emerging technologies (e.g. nanotechnology, biotechnology, etc.)
- Applying liquid chromatography/mass spectrometry techniques and the characterization of pharmaceuticals which utilize novel delivery mechanisms and/or protein components



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- Researching 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
- Investigating NMR in the study of protein based drug products

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 ORA 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 ORA in Jamaica, New York. Participants do not become employees of ORA, NRL, FDA or the program administrator, and there are no fringe benefits paid.

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).

Qualifications The applicant must have received a Ph.D. 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

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
 - **Chemistry and Materials Sciences** ([4](#)👁)
 - **Physics** ([1](#)👁)