

Opportunity Title: Bioanalytical Fellowship - FDA CDER Opportunity Reference Code: FDA-CDER-2019-0363

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

Reference Code FDA-CDER-2019-0363

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 An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland.

> The Bioanalytical group of the Division of Applied Regulatory Science (DARS) in the Office of Clinical Pharmacology (OCP) is involved in a number of projects related to the pharmacokinetic evaluation of both small and large molecules. DARS provides bioanalytical support for in vitro (animal and clinical) in vivo projects including drug transport and metabolism investigations. This project in DARS will provide training in a variety of advanced analytical and bioanalytical assays from method development to experimental or test sample analysis including the process of method validation.

Under the guidance of a mentor the participant will be involved in:

- identifying novel analytical needs for bioanalytical portion of Divisional projects
- · searching literature for existing approaches
- formulating novel approaches to analytical needs

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 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 The qualified candidate must have received a master's or doctoral degree in health sciences, chemistry, biology, pharmaceutical sciences or a related field. Degree must have been received within five years of the appointment start date.

Preferred skills:



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- Training in bioanalytical techniques including familiarity with liquid chromatography, mass spectrometry, immunocapture sample clean-up, and ligand binding assays
- Knowledge of bioanalysis, mass spectrometry, chromatography, immunogenicity assays or metabolism studies

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- Discipline(s):
 - Chemistry and Materials Sciences (<u>3</u> <a>●)
 - Engineering (1●)
 - Environmental and Marine Sciences (1.4)
 - Life Health and Medical Sciences (45.●)

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