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Opportunity Title: FDA Bioanalytical Fellowship
Opportunity Reference Code: FDA-CDER-2020-0493

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

Reference Code FDA-CDER-2020-0493

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@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 6/30/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Translational Sciences/Office of Clinical Pharmacology located in Silver Spring, Maryland.

This project in the Office of Clinical Pharmacology, Division of Applied Regulatory Science (DARS) will play a key role in advancing the regulatory research within DARS by contributing to developing and validating bioanalytical assays to support preclinical and clinical PK and PK/PD studies. Specifically, the projects will contribute to clinical pharmacodynamic biomarker platform for biosimilar drugs by evaluating candidate biomarkers, establishing the bioanalytical assays needed to support their measurement in animals and humans. This project will support the clinical studies of opioids to investigate the effect of psychotropic drugs on opioids-induced respiratory depression which will eventually inform the labelling text on concurrent use of opioids and psychotropic drugs and aims at understanding why certain drugs elicit toxicity in humans which went undetected in animal studies.

Under the guidance of a mentor the participant will learn how to develop assays to quantify the drug and/or its metabolite levels in animal blood (plasma or serum) and tissues, validate robust bioanalytical assays for quantifying small and large drug molecules and biomarkers, and learn about automating sample preparation in a bioanalytical lab for higher throughput of preclinical and clinical pharmacokinetic samples. This training will prepare the participant for a successful career transition into regulatory science research.

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.

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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 master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- 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** (3 👁)
  - **Engineering** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)