Opportunity Title: Abuse Deterrence Fellowship - Center for Drug Evaluation and Research
Opportunity Reference Code: FDA-CDER-2018-0285

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

Reference Code FDA-CDER-2018-0285

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 research opportunity is available at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs/Office of Research and Standards.

Scientific research is needed for the proper evaluation and approval of generic drugs. This project will support projects for all therapeutic categories of generic drugs and will encompass projects from in vitro to in vivo studies. Results will support development of guidances, recommendations to industry, and regulatory review, This project will support the development of general and product-specific guidances, inform recommendations to industry and help expand the reviewer knowledge base, publish results in scientific journals and present at scientific conferences.

The project will be focused on the following topic areas: (1) complex active ingredients, formulations or dosage forms, (2) complex routes of delivery, (3) complex drug-device combinations, (4) tools and methodologies for bioequivalence and substitutability evaluation where under the guidance of a mentor the participant may be involved in: yielding measurements from in vitro, animal and clinical studies as well as predictive data from modeling tools.

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 12 months, 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, MD area. Participants do not become employees of FDA or

the program administrator, and there are no fringe benefits paid.

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 (3) of the past five (5) years in order for FDA to be able to complete a background check.

Qualifications

A Ph.D., M.D., Pharm.D., or other qualified scientific advanced degree(s) received within five years of the desired starting date are required.

Knowledge of equivalence standards for generic abuse-deterrent opioid drug products.
Relevant familiarity in meta-analysis of current abuse deterrent formulations, technologies and in vitro methodologies for evaluating abuse deterrence for solid opioid drugs related abuse-deterrent formulations is preferred

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1)
  - **Life Health and Medical Sciences** (45)
  - **Mathematics and Statistics** (1)