Opportunity Title: Research Administration Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2017-0001

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

Reference Code FDA-CDER-2017-0001

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 research opportunity is available at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in the Office of Generic Drugs/Office of Research and Standards. The Office of Generic Drugs (OGD) promises the American public that approved generic products are therapeutic equivalents that can be freely interchanged with the brand name product. To help protect patients from generic substitution of inequivalent products, OGD conducts regulatory science research to develop new methods and approaches to evaluate product quality and equivalence. OGD translates scientific advances and research findings into regulatory review policy for OGD application review.

The goals of the project involve the following: 1) analyzing data from external research studies to develop recommendations for complex generic products; ensure generic substitution; conduct analysis of internal FDA data to help develop equivalence standards; evaluate post-market data; evaluate approved generic products; conduct laboratory research to characterize complex reference products, and 2) build databases, quantitative physiological, and mechanistic models to support new approaches to bioequivalence.

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

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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.

Qualifications

Applicants must have received a bachelors or masters degree in social sciences, research administration, health administration, health communications public health, business administration, or related degree within five years of the desired starting date, or completion of all requirements for the degree should be expected prior to the start date. Applicants with proficiency in Word, Excel and Visio are desired.

Eligibility Requirements

- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Communications and Graphics Design** (3 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Social and Behavioral Sciences** (4 👁)