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Opportunity Title: FDA Pharmacy Compounding Regulatory Analysis Fellowship
Opportunity Reference Code: FDA-CDER-2019-0420

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

Reference Code FDA-CDER-2019-0420

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 12/31/2019 3:00:00 PM Eastern Time Zone

Description Research opportunities are available either in the Office of New Drugs or Office of Compliance, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

In 2013, FDA began implementing the drug compounding provisions of the Drug Quality and Security Act. Drug compounding by pharmacists or physicians is a long standing tradition in which health care professionals use bulk chemical substances to create oral, topical or other medications that are not otherwise commercially available as drug products. These compounded drug products are intended to meet the needs of individual patients who are perceived to derive unacceptable health outcomes from FDA approved drugs. The new FDA program evaluates the safety and effectiveness of many bulk chemicals to treat various medical conditions, based on a public nomination process. This evaluation process will determine which bulk substances are appropriate for continued drug compounding.

Under the guidance of a mentor, the selected participant will research specific chemical substances and medical conditions that will be subject to FDA rulemaking. This may include providing summary data and analysis of available scientific literature published or submitted to the public docket, and other activities such as comprehensive literature search on specific chemical substances and the scientific information available regarding their use as drugs, summary and analysis of key findings, limitations and published data.

***Although the application deadline is December 31, applications will be reviewed on a rolling-basis.**

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 three 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, 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 be currently pursuing a bachelor's master's or doctoral degree in one of the relevant fields.

Preferred skills:

- Ability to analyze and summarize findings from the literature
- Excellent writing skills
- Experience with clinical trials

Eligibility Requirements

- **Degree:** Currently pursuing a Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)