

Opportunity Title: Drug Safety & Risk Evaluation Fellowship - Center for Drug Evaluation and Research

Opportunity Reference Code: FDA-CDER-2018-0298

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

Reference Code FDA-CDER-2018-0298

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.

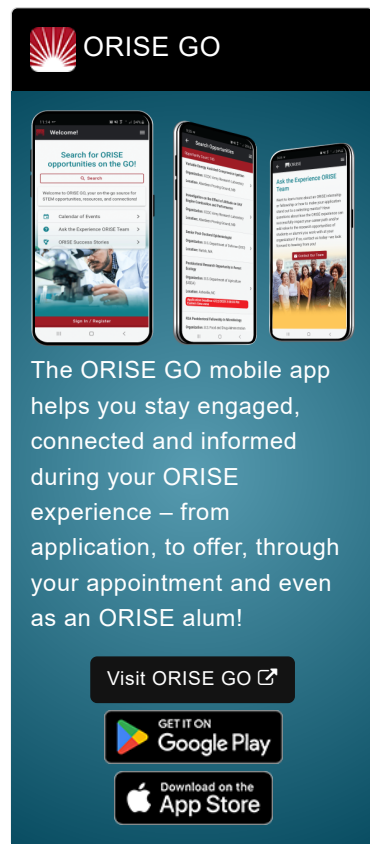
This project in The Office of Surveillance and Epidemiology (OSE) and Office of Medication Error Prevention and Risk Management (OMEPRM) will focus on addressing Risk Evaluation and Mitigation Strategies (REMS) related issues associated with currently marketed drug products by researching scientific methods related to REMS implementation and evaluation for marketed drug products, thereby advancing regulatory decision making. Successful completion and publication of this project may develop new evidence-based risk management tools and methods, improve the quality and effectiveness of REMS programs while minimizing program-related burden and access barriers, and advance the science of REMS assessment.

Under the guidance of a mentor, the participant will receive training in conducting a systematic review of the literature of the comparative effectiveness of tools used in REMS; evaluating the impact of REMS elements on healthcare providers' and patients' knowledge and ability to positively impact behavior; and cataloging of all REMS tools and assessment of effectiveness, individually and across REMS programs.

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 Bachelor's or master's degree in health sciences, or doctorate in Pharmacy, earned within the past five year, required. PGY1 Residency also eligible.




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Familiarity with epidemiology and survey methodology desired.

- Eligibility**

Requirements
- **Degree:** Any degree .
 - **Discipline(s):**
 - **Communications and Graphics Design** ([1](#)👁)
 - **Life Health and Medical Sciences** ([2](#)👁)
 - **Other Non-Science & Engineering** ([1](#)👁)
 - **Social and Behavioral Sciences** ([1](#)👁)