Opportunity Title: Microphysiological Systems-Drug Development Tools - FDA CDER
Opportunity Reference Code: FDA-CDER-2017-0102

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

Reference Code FDA-CDER-2017-0102

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 Translational Sciences/Office of Clinical Pharmacology.

The Center for Drug Evaluation and Research (CDER), Office of Translational Sciences (OTS), Office of Clinical Pharmacology (OCP), Division of Applied Regulatory Science (DARS) is currently investigating liver microphysiological systems as drug development tools. DARS seeks to move new science into the regulatory review process and close the gap between scientific innovation and medical product review. Given the high potential of microphysiological systems as pre-clinical drug testbeds that can reduce the need of animal testing and better predict clinical outcomes of drugs, DARS is actively evaluating the shift of paradigm in drug testing that can result in standardizing assays with these innovative devices.

Under the guidance of a mentor the participant may be involved in drug toxicity studies, drug-drug interactions and drug mechanisms of action in different hepatic models. The participant may be directly involved in the assembly, operation, maintenance, evaluation and use of liver microphysiological systems for assaying human-specific effects of drugs and drug-drug interactions in physiological settings.

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 the FDA. The initial appointment is full-time for 12 months, but may be renewed upon recommendation of the 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 the FDA in the Silver Spring, MD area. Participants do not become employees of the FDA or the program administrator, and there are no fringe benefits paid.

Opportunity Title: Microphysiological Systems-Drug Development Tools - FDA CDER
Opportunity Reference Code: FDA-CDER-2017-0102

Qualifications Fellowship candidates would have a Doctoral degree in bioengineering/biomedical engineering, human biology, pharmacology, human physiology or related fields with a strong emphasis on hepatic function/toxicity, cellular biology, and in vitro testing of cell function using microsystems or culture systems with engineered microenvironments.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (2 👁)
  - **Science & Engineering-related** (1 👁)