Opportunity Title: Absorption Modeling for Quality Control Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2017-0065

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

Reference Code FDA-CDER-2017-0065

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).

The overall purpose of this program is to perform a proof of concept study and establish basis for building a quantitative risk assessment tool using antiviral drugs as model drugs, to evaluate the impact of potential changes in the critical quality attributes on the clinical performance under situations of changes in Critical Material Attributes (CMAs)/Critical Process Parameters (CPPs).

Under the guidance of a mentor, the participant may be involved in:

- Establishing a basis for developing a new tool for quantitative risk assessment and accelerate decision making in the review process.
- Assisting in the verification of the design space of critical quality attributes such as particle size etc.
- Studying and defining appropriate methods to mitigate the risk of the changes in CMAs/CPPs on drug safety/efficacy.

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 (HSPD12) 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 A Doctoral or Master's degree in pharmaceutical sciences or related area with

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familiarity in pharmacokinetic modeling received within five years of the appointment start date.

Eligibility Requirements

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