

Opportunity Title: Chemistry Fellowship - CDER Opportunity Reference Code: FDA-CDER-2017-0040

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

Reference Code FDA-CDER-2017-0040

How to Apply A complete application consists of:

- An application
- Transcripts <u>Click here for detailed information about acceptable</u> 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 <u>FDArpp@orau.org</u>. Please include the reference code for this opportunity in your email.

Description A postgraduate research opportunity is available at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in the Office of Pharmaceutical Quality/Office of Testing and Research.

A pivotal question is usually raised during the quality review process of ANDAs/NDAs: "How is the quality of a drug product related to its clinical performance?" One obstacle is the lack of a reliable/reasonable in vitro surrogate test for the in vivo drug product performance. The proposed project will focus on the development and evaluation of a bi-phasic dissolution method which may better predict in vivo results.

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 St. Louis, MO 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 doctoral degree in physical sciences, analytical chemistry, chemistry, pharmaceutical science, or chemical engineering within five years of the desired starting date. Experience with in vitro dissolution testing, UV/vis, HPLC, automation, physical characterization, texture instrument, inForm system is preferred.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
 - Discipline(s):
 - Chemistry and Materials Sciences (4.)
 - Engineering (<u>4</u> [●])
 - Environmental and Marine Sciences (1.)

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• Life Health and Medical Sciences (45)