Opportunity Title: Quality Control of Generic Drugs Using MALDI-TOF/TOF MS Fellowship-CDER
Opportunity Reference Code: FDA-CDER-2016-0011

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

Reference Code FDA-CDER-2016-0011

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 fellowship opportunity is currently available with the Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Quality, Office of Testing and Research, Division of Pharmaceutical Analysis, of the U.S. Food and Drug Administration in St. Louis, MO.

Generic drug products are susceptible to quality control issues, including increased impurities, incorrect pharmaceuticals, and wrong dosages. For instance, a leading generic drug provider to the U.S. has been previously under investigation for deficiencies with their drug manufacturing processes, involving beta-lactam cross contamination, impurities in pantoprazole, and incorrect dosages of atorvastatin (trade name Lipitor®). The principal aim of this research proposal is to analyze generic drugs for quality control purposes using high-throughput, high resolution matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF/TOF MS)

This project will focus on developing rapid MS methods for quality assessment of drugs used to treat or reduce cardiovascular disease since it is the leading cause of death in the U.S. Statins are a class of drugs that prevent cardiovascular events by lowering cholesterol, and statins will be targeted for evaluation of drug product quality in this research. Angiotensin II receptor blockers are another class of drugs that reduce cardiovascular events by treating hypertension (elevated blood pressure). Angiotensin II receptor blockers will be targeted for analysis in this proposal.

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

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interagency agreement between DOE and FDA. 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, Missouri, area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications

- A PhD degree or be enrolled in a PhD program in analytical chemistry or related field and experience with mass spectrometry are required.
- Experience in the characterization of small molecules using tandem MS and quantitation using a TOF mass spectrometer is highly desirable.
- Experience with using a Bruker MALDI mass spectrometer and a Thermo nano LC is a plus.
- Experience conducting analyses in a laboratory with the ability to develop and optimize methods.
- Demonstrated reporting data in a timely manner in the forms of a laboratory notebook, technical reports, and manuscripts.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Academic Level(s):** Post-Bachelor's, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (6 👁)
  - **Life Health and Medical Sciences** (3 👁)
  - **Physics** (16 👁)