

Opportunity Title: Solution NMR Spectroscopy on Complex Drug Product

Fellowship - FDA CDER

Opportunity Reference Code: FDA-CDER-2018-0184

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

Reference Code FDA-CDER-2018-0184

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.

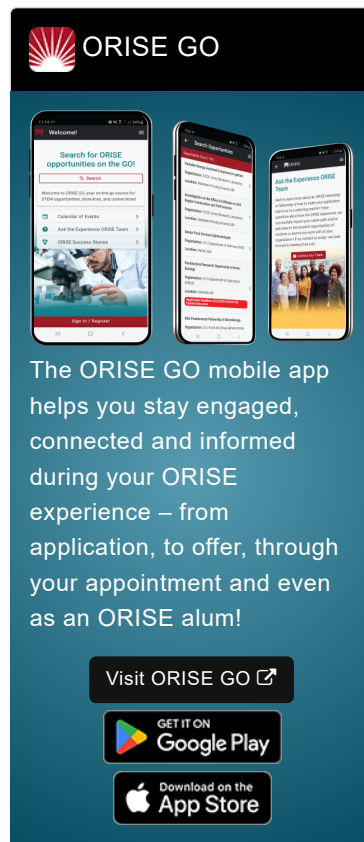
If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

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

This project seeks to establish a scientific basis for quantitative assessment of Two-Dimensional Nuclear Magnetic Resonance (2D NMR) spectra similarity through publications and presentations. This research will give Chemistry, Manufacturing and Controls (CMC) reviewers the information needed to evaluate physiochemical differences reflected in a 2D spectra comparison if presented by a sponsor.

Under the guidance of a mentor, the selected fellow will conduct research on complex generic drugs using nuclear magnetic resonance (NMR) and other analytical methods like AUC, DLS and FPLC. This research will aim to develop validated methods to assess the identity, purity and content of complex drugs in comparison to the reference listed drug. The participant will conduct analysis and experimentation in the laboratory utilizing prescribed procedures (protocols, standard operating procedures, etc.), and will document and report data in a timely manner according to regulatory guidelines. S/he will perform much of their research on 500 and 850 MHz Bruker spectrometers in the FDA White Oak Campus NMR Facility.

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, DOE or the program administrator, and there are no employment-related benefits.

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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 complete a background check.

Qualifications Applicants must have received a PhD in analytical chemistry, natural product chemistry, pharmaceutical science, biopharmaceutics, biochemistry or biophysics. Familiarity in the field of chemical composition analysis of small molecule mixture, natural product, proteins or sugar/glycan using NMR is preferred.

- Eligibility Requirements**
- **Degree:** Doctoral Degree received within the last 60 month(s).
 - **Discipline(s):**
 - **Chemistry and Materials Sciences** ([2](#) )
 - **Life Health and Medical Sciences** ([1](#) )

Affirmation Have you lived in the U.S. for three of the past five years?