Opportunity Title: FDA Postdoctoral Fellowship in Compounded Drug Analysis
Opportunity Reference Code: FDA-CDER-2023-1295

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

Reference Code FDA-CDER-2023-1295

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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
- One educational or professional recommendation

All documents must be in English or include an official English translation.

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

Application Deadline 9/30/2023 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

The project is in the Office of Testing and Research (OTR), Office of Pharmaceutical Quality (OPQ). Some patients require the individualized attention of a compounded drug to meet their specific needs. Compounded drugs are not FDA-approved and present a risk to patients. To prevent potential widespread quality issues related to compounded drugs the Drug Quality and Security Act gave FDA direct authority to oversee non-prescription-based large-scale compounding in 2013. FDA also conducts risk-based surveillance inspections of outsourcing facilities, and of state-licensed pharmacies of which the agency is aware. However, it is challenging to verify the quality of a compounded drug because compounded drugs are often lack of compliant testing methods. This research opportunity will focus on developing and validating new analytical methods and techniques to support the quality assessment of compounded drugs.
Under the guidance of the mentor, the participant will take part in development and validation of an analytical method based upon multiple standards for industry guidance. Instrumental techniques will be HPLC, RAMAN and NMR spectroscopy and LC-MS spectrometry and other appropriate analytic tools. Techniques for sample preparation and drug stability study will also be explored.

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 one year, 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, Missouri area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate should have received or be currently pursuing a doctoral degree in one of the relevant fields. Degree must have been received within the last 5 years.

Preferred qualifications:

- Solid Organic Chemistry and Biochemistry knowledge
- A background in analytical science
- Experience in NMR spectroscopy and liquid chromatography

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 9/30/2023 12:00:00 AM.

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- **Discipline(s):**
  - **Chemistry and Materials Sciences** (3 👁)
  - **Life Health and Medical Sciences** (1 👁)

Affirmation I have lived in the United States for at least 36 out of the past 60 months (36 months do not have to be consecutive). I have read the FDA Ethics Requirements.