Opportunity Title: FDA Analytical Chemistry Research for the Detection of Fraudulent COVID-19 Therapeutics
Opportunity Reference Code: FDA-ORA-2023-02

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

Reference Code FDA-ORA-2023-02

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
- 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.OC.other@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 4/13/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity for a motivated and independent individual is currently available at the U.S. Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Regulatory Science (ORS), Office of Medical Products and Specialty Laboratory Operations, Forensic Chemistry Center located in Cincinnati, OH.

This project aims to develop handheld Raman spectroscopy, portable Fourier transform infrared (FT-IR) spectroscopy, and high-resolution mass spectrometry (HRMS) methods capable of rapidly analyzing the contents of products labeled or promoted to treat COVID-19. Numerous products have been publicized as treatments for COVID-19, including injections and oral dosage forms. Some of these products have received emergency use authorization, while others have been used for treating COVID-19 without approval. In fact, the FDA has recently issued warning letters to firms selling fraudulent products marketed to treat COVID-19, which threaten the integrity of the U.S. pharmaceutical supply chain. It is expected that adulterated, substandard, unapproved and/or counterfeit versions of the approved products will continue to be produced and sold. These violative products may be detrimental to consumers' health by lacking the expected active pharmaceutical ingredient or by containing undeclared and potentially harmful substances. Consequently, analytical methods capable of detecting such compromised products are necessary. It is expected that the development of rapid screening methods will help reduce the distribution of fraudulent products.

Under the guidance of a mentor, the ORISE fellow will:

- 1. Learn theoretical and practical knowledge from experts in several analytical chemistry techniques, including Raman spectroscopy, FT-IR spectroscopy, liquid chromatography, mass spectrometry, and ambient ionization, using modern instrumentation.

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- 2. Develop/enhance critical thinking and independent problem-solving capabilities.
- 3. Improve communication and relationship skills by participating in an interdisciplinary team environment.
- 4. Enhance speaking and/or writing skills by presenting and/or publishing the results of the project at relevant meeting(s) and/or in relevant journal(s), respectively.
- 5. Gain experience at the country's only food and drug forensics laboratory while having a significant impact on public health.

The participant will receive a monthly stipend commensurate with educational level and experience. **The current stipend for this opportunity is $76,000 per year plus $2,500 for project-related travel. Relocation expenses will not be provided.**

Anticipated Appointment Start Date: June 18, 2023; start date is flexible

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.** Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Cincinnati, Ohio 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 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 a master's or doctoral degree in one of the relevant fields, or be currently pursuing one of the degrees with completion before December 31, 2023. Degree must have been received within the past five years.

Preferred skills:

- Laboratory research experience using mass spectrometry, liquid chromatography, and/or IR/Raman spectroscopy.
- Experience conducting cooperative scientific studies.
- Clear and effective oral and written communication skills.

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The ideal candidate may also possess the following:

- Familiarity with Xcalibur, TraceFinder, and/or CompoundDiscoverer software.
- Familiarity with Omnic software.
- Familiarity with data plotting software (e.g., Origin, R, etc.).

Point of Contact Sherry

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 12/31/2023 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (2 👁)
  - **Physics** (2 👁)

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.)