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Opportunity Title: FDA Analytical Methods for Handheld and Field Portable Devices Fellowship
Opportunity Reference Code: FDA-OC-2025-0001

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

Reference Code FDA-OC-2025-0001

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click 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 6/10/2025 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in the Office of the Commissioner (OC), located at Cincinnati, Ohio.

Research Project: The FDA/Office of the Commissioner (OC) / Forensic Chemistry Center (FCC) in collaboration with the Center for Drug Evaluation and Research (CDER) is developing methods to detect active pharmaceutical ingredients (APIs) in suspect drug products using field portable instruments that are currently being utilized at international mail facility satellite laboratories to help prevent dangerous products from reaching the U.S. supply chain. The primary goal of this research is to expand the number of APIs that can be identified using the toolkit devices, which will reduce the number of samples that require costly and time-consuming additional analysis at an offsite laboratory to achieve the results necessary to support refusal and/or destruction. Ultimately, the research will significantly limit the number of dangerous goods reaching US consumers.

An additional goal of this project is to evaluate the combination of current toolkit results with chemometrics as well as determine the performance of other portable instruments to potentially overcome fundamental limitations of the current toolkit. We will aim to develop methods for approximately 60 FDA-priority APIs that belong to a wide variety of drug classes. Our goal is to be successful for >80% of these compounds, which we believe is both reasonable and realistic based on previous experience. We expect that <10% of the APIs of interest will simply not be amenable for detection due to unfavorable bonds, structure, etc. Simply put, we expect to increase the

number of compounds able to be detected by the satellite laboratory toolkit by approximately 50 FDA-priority APIs. As a point of reference, about 40 new compounds are added to the toolkit libraries per year using routine extraction methods, so it is realistic to expect that modified extraction methods can be developed for 50 unique APIs over the course of one year by a dedicated analyst. The three-pronged approach listed below will be used to achieve the aims of this project:

- Improve the currently non-optimized extraction methods followed by detection using portable mass spectrometer, FT-IR spectroscopy and Raman spectroscopy.
- Expand surface enhanced Raman spectroscopy (SERS) methods for the handheld device.
- Improve API detection capabilities on multi-API drug samples.

Scope of tasks will include, but not be limited to:

- Design and validate analytical methods using field portable devices to detect unlabeled active pharmaceutical ingredients (APIs) in suspect pharmaceutical products.
- Use different portable analytical techniques such as ambient ionization mass spectrometry, gas chromatography with mass spectrometric detection (GC/MS), FT-IR spectroscopy, Raman spectroscopy, and surface enhanced Raman spectroscopy to detect bulk and trace level APIs in finished dosage products.
- Design wet chemistry techniques to isolate analyte of interest in multi-component samples.
- Perform complex data analysis and interpret experimental results.
- Prepare manuscripts and reports.
- Publish research findings in high-impact peer reviewed technical journals and conferences; and stay current on recent research in the field by reading published literature.
- Make presentations at scientific meetings and seminars.

Learning Objectives: This opportunity provides the selected research fellow with an excellent learning opportunity to:

- Collaborate with FDA scientists in diverse research laboratories throughout the project
- Learn about synthesis approaches and multiple analytical techniques
- Present research finding at various national and/or international scientific meetings
- Author peer-reviewed journal articles

Anticipated Appointment Start Date: 2025. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for seven months, but an additional year may be renewed upon recommendation of FDA and is contingent on the availability of funds.

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Level of Participation: The appointment is full time.

Citizenship Requirements: This opportunity is available to U.S. citizens only.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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 be currently pursuing or have received a bachelor's, master's, or doctoral degree in the one of the relevant fields (e.g. chemistry, material sciences, or a closely related field). Degree must have been received within the past five years, or currently pursuing.

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Preferred skills:

- Extensive experience with analytical chemistry method development and validation.
- Experience with a range of characterization instruments such as ambient ionization mass spectrometry, GC-MS, -IR spectroscopy, Raman spectroscopy, and surface enhanced Raman spectroscopy.
- Experience with wet chemistry techniques.
- Excellent oral and written communication skills.
- Ability to design experiments, conduct independent research and contribute to peer-reviewed publications.
- Ability to act as an independent researcher with a high level of scientific judgment and initiative, as well as to collaborate with other researchers in a diverse team environment.
- Strong organizational and record-keeping skills.

Point of Contact Sherry Foster

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Earth and Geosciences** (21 👁)
  - **Engineering** (27 👁)
  - **Environmental and Marine Sciences** (14 👁)
  - **Mathematics and Statistics** (11 👁)
  - **Physics** (16 👁)
  - **Science & Engineering-related** (1 👁)
- **Veteran Status:** Veterans Preference, degree received within the last 120 month(s).

Affirmation I am a U.S. citizen, or 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.) and I have read the FDA Ethics Requirements.