Opportunity Title: FDA Drug Product Quality Assessment
Opportunity Reference Code: FDA-CDER-2026-0072

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

Reference Code FDA-CDER-2026-0072

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.CDER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 5/8/2026 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 immediately with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in St. Louis, Missouri.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This effort covers more than just medicines.

Research Project: Quality concerns of benzene contamination have been recognized in drug products across many different formulations. Offices within OPQ are collaborating to develop and validate a universal gas chromatography-mass spectrometry (GC-MS) method to assess drug products for benzene contamination. This project aims to develop a standardized test method for assessing benzene content, which will help in making informed regulatory decisions. Results from these studies will be used to evaluate current industry guidance limits and help to identify where to direct surveillance efforts.

Learning Objectives: Under the guidance of the mentor, you will gain knowledge on the development of an analytical method based upon multiple standards for industry guidance, and the quality assessment of drug products for benzene contamination. You will conduct data interpretation and evaluation, gain regulatory process knowledge, conduct experiments, and evaluate sample formulae and matrices to support this project. Due to the broad field of sample matrices on the market, you will participate with the team's statisticians to gather data from agency databases to identify ideal samples for analysis. You will participate in cross laboratory studies

where you will perform sample analyses and review results from other independent laboratories participating in surveillance testing. Instrumental techniques like gas chromatography and mass spectrometry will be heavily employed, so training in that area will be provided. Sample preparation techniques will also be explored, to find the most effective means to quantify trace benzene in a variety of sample types.

Mentor: The mentor for this opportunity is Matthew Stark (Matthew.Stark@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: 2026. Start date is flexible and will depend on a variety of factors.

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

Level of Participation: The appointment is full time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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.

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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. Degree must have been received within the past five years.

Preferred Skills:

- Previous experience in analytical chemistry and in gas chromatography

Point of Contact

Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)

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.)

AND

I have read the FDA Ethics Requirements.