Opportunity Title: FDA Advanced Evaluation of Postmarket Product Quality Reports
Opportunity Reference Code: FDA-CDER-2026-0071

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

Reference Code FDA-CDER-2026-0071

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 5/31/2026 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 Silver Spring, Maryland.

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: The project includes understanding manufacturing deviations submitted for CDER-regulated drugs using CDER post market report management database and tools. The focus of the project will be to conduct data analysis and research different methodologies to identify and compile clusters and/or trends for potential product quality signals. During the appointment, you will help explore important parameters in cluster and/or trend identification to help with the development of an algorithm that can be used for signal detection. Through utilizing appropriate platforms and applying modern statistical approaches, such as data mining, natural language processing and deep learning, complex data and large data can be studied to deliver faster and more accurate results along with establishment of a detection tool.

Learning Objectives: Under the guidance of the mentor(s), you will be able to explore CDER post market report program, understand the process on how these reports are handled, gain knowledge with these complex datasets, and contribute in tool development effort. You will also learn basic concepts of manufacturing process and CGMP practices with the exposure to various databases and statistical tools and platforms.

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Mentor: The mentor for this opportunity is Hui I Tom (Hui-I.Tom@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 part time or 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.

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:

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- 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 bachelor's, master's, or doctoral degree in one of the relevant fields. Degree must have been received within the last 60 months, or be currently pursuing their degree.

Preferred skills/knowledge:

- Basic knowledge in pharmaceutical manufacturing process and CGMP compliance
- Previous experience with and mining complex and large data sets
- Knowledge and experience developing predictive analytics with modern statistical, artificial intelligence or machine learning techniques

Point of Contact Ashley

Eligibility Requirements

- **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)
  - **Computer, Information, and Data Sciences** (17)
  - **Engineering** (29)
  - **Life Health and Medical Sciences** (51)
  - **Mathematics and Statistics** (11)

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.