Opportunity Title: FDA Developing Improved Regulatory Assessment Tools from Pre-approval and Pre-license Inspection Product Quality Data
Opportunity Reference Code: FDA-CDER-2025-1468

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

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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 2/28/2025 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 Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Manufacturing Assessment (OPMA), Office of Pharmaceutical Quality (OPQ) located at 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 work covers more than just medicines.

Research Project: This project is in the Office of Pharmaceutical Manufacturing Assessment (OPMA), Office of Pharmaceutical Quality (OPQ). This project involves participation in research whose objective is to provide data and evidence that can help inform the communications, inspectional, and regulatory activities of OPQ. OPQ integrates the assessment of drug applications with the evaluation of manufacturing facilities, leading to a single, more informed quality assessment. OPQ/OPMA recognizes that currently a great amount of regulatory knowledge has been accumulated during the review of Biologics License Applications (BLAs) and New Drug Applications (NDAs). However, it is still a paramount challenge to easily share such knowledge to guide the review of drug manufacturing facilities and facility inspections since such a knowledge base is dispersed and “hidden” in different parts of the Agency. This project will support the advancement of continuous improvement initiatives for regulatory review to develop and improve facility evaluations

and inspection protocols for CDER review programs.

Learning Objectives: Under the guidance of the mentor the participant will be trained on pharmaceutical science, laws and regulations related to pharmaceutical quality, and lifecycle management of manufacturing assessments for drug products to support regulatory decision making. Training in data analytics and modeling to gather and analyze the outcomes of manufacturing assessments and facility inspections from various regulatory knowledge management platforms. As well as training in project management skills leveraging curated data to analyze current deficiency trends in quality manufacturing assessment and facility evaluations/inspections to inform internal decision making and external communication strategies.

Anticipated Appointment Start Date: 2024/2025. 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.

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:

- 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 master's or doctoral degree in the one of the relevant fields. Degree must have been received within the past five years, or anticipated to be received by 3/31/2025.

Point of Contact Sara Beth Hensley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 3/31/2025 12:00:00 AM.
- **Discipline(s):**
  - **Engineering** (1)
  - **Life Health and Medical Sciences** (5)

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.