Opportunity Title: FDA Fellowship - Applications of Artificial Intelligence, Modeling, and Simulation to Pharmaceutical Manufacturing and Product Characterization
Opportunity Reference Code: FDA-CDER-2026-0086

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

Reference Code FDA-CDER-2026-0086

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 7/17/2026 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 within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at White Oak, 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. These efforts cover more than just medicines.

Research Project: The U.S. Food and Drug Administration (FDA) is seeking an ORISE fellow to support research at the intersection of artificial intelligence (AI), computational modeling, and simulation as applied to pharmaceutical manufacturing and product characterization. This fellowship offers a unique opportunity to contribute to cutting-edge regulatory science initiatives aimed at advancing the safety, efficacy, and quality of pharmaceutical products. You will engage in research activities exploring the development, evaluation, and application of AI-based methods, mechanistic models, and simulation frameworks relevant to pharmaceutical manufacturing processes and product characterization.

Areas of focus may include but are not limited to exploration of machine learning and deep learning approaches for tasks such as process monitoring, fault detection, real-time release testing, and the prediction of quality attributes from process data. The broader area of focus may include

Opportunity Title: FDA Fellowship - Applications of Artificial Intelligence, Modeling, and Simulation to Pharmaceutical Manufacturing and Product Characterization
Opportunity Reference Code: FDA-CDER-2026-0086

application of computational and data-driven methods to support the characterization of pharmaceutical products, including analysis of physicochemical properties, structural features, and performance-related attributes. The project will contribute to the development of scientific frameworks, best practices, and evaluation methodologies that inform FDA's regulatory approach to AI- and model-based submissions in pharmaceutical manufacturing.

Learning Objectives: Under the guidance of a mentor, you will learn to:

1. Apply AI and machine learning techniques to real-world pharmaceutical manufacturing and product characterization challenges.
2. Develop and evaluate computational models and simulations relevant to pharmaceutical unit operations and quality assessment.
3. Interpret and analyze complex pharmaceutical process and product data to extract actionable scientific insights.
4. Gain familiarity with FDA regulatory frameworks and standards governing AI- and model-based approaches in pharmaceutical manufacturing.
5. Communicate research findings effectively through scientific reports, manuscripts, and presentations.
6. Collaborate within a multidisciplinary research environment spanning regulatory science, engineering, and data science.

Mentor: The mentor for this opportunity is Jayanti Das (jayanti.das@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

Opportunity Title: FDA Fellowship - Applications of Artificial Intelligence, Modeling, and Simulation to Pharmaceutical Manufacturing and Product Characterization
Opportunity Reference Code: FDA-CDER-2026-0086

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.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

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.