Opportunity Title: FDA Fellowship - Mechanistic Modeling and Simulation
Opportunity Reference Code: FDA-CDER-2026-0141

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

Reference Code FDA-CDER-2026-0141

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.

Connect with ORISE...on the GO! Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

Application Deadline 9/25/2026 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), Office of Pharmaceutical Quality (FDA/CDER/OPQ), located in 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. This effort covers more than just medicines.

Research Project: The U.S. Food and Drug Administration's Center for Drug Evaluation and Research, Office of Pharmaceutical Quality (FDA/CDER/OPQ), is seeking an ORISE fellow to gain experience in regulatory science research supporting pharmaceutical product quality. The project will focus on the development and application of artificial intelligence, machine learning, mechanistic modeling, mathematical modeling, and simulation methods to pharmaceutical manufacturing and product characterization.

The fellow will collaborate with and learn from multidisciplinary FDA scientists to develop data-driven and first-principles models and evaluate

how they can be used to improve understanding of pharmaceutical products and manufacturing processes. The research will contribute to the development of scientific principles, evaluation strategies, and best practices for the use of computational models and AI-enabled methods in pharmaceutical quality.

Potential research topics include:

1. Machine learning and deep learning methods for process monitoring, anomaly detection, fault diagnosis, and prediction of critical quality attributes.
2. Data-driven models for process optimization, real-time release testing, and manufacturing process control.
3. Mechanistic and mathematical models of pharmaceutical unit operations, transport phenomena, material behavior, and product performance.
4. Hybrid modeling approaches that combine mechanistic knowledge with machine learning.
5. Model calibration, validation, uncertainty quantification, sensitivity analysis, and assessment of model credibility.
6. Computational characterization of pharmaceutical products using physicochemical, structural, formulation, manufacturing, and performance-related data.
7. Evaluation of AI- and model-based methodologies submitted in support of pharmaceutical development, manufacturing, and quality assessment.

Learning Objectives: Under the guidance of an FDA mentor, you will have opportunities to:

1. Learn to develop and apply AI and machine learning methods to pharmaceutical manufacturing and product quality challenges.
2. Gain experience constructing and evaluating mechanistic, mathematical, statistical, and hybrid models of pharmaceutical systems.
3. Learn to analyze complex manufacturing, formulation, material, and product-performance data to support scientific and regulatory objectives.
4. Develop skills in model verification, validation, uncertainty quantification, and credibility assessment methods.
5. Build knowledge of regulatory science principles and FDA frameworks related to pharmaceutical quality and model-informed approaches.
6. Learn to translate computational and modeling results into scientifically defensible conclusions that support regulatory assessment activities.
7. Gain experience preparing technical reports, scientific manuscripts, presentations, and other research communications.
8. Develop collaborative skills by working with scientists, engineers, statisticians, data scientists, and regulatory reviewers on interdisciplinary projects.

Mentor: The mentor for this opportunity is Jianan

Zhao (jianan.zhao@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: September 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.

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;

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- 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):**
  - **Chemistry and Materials Sciences** (12)
  - **Communications and Graphics Design** (2)
  - **Computer, Information, and Data Sciences** (17)
  - **Earth and Geosciences** (21)
  - **Engineering** (29)
  - **Environmental and Marine Sciences** (14)
  - **Life Health and Medical Sciences** (51)
  - **Mathematics and Statistics** (11)
  - **Physics** (16)
  - **Science & Engineering-related** (1)

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.