Opportunity Title: FDA Fellowship in Generic Opioid Bioequivalence and Safety Research
Opportunity Reference Code: FDA-CDER-2026-0169

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

Reference Code FDA-CDER-2026-0169

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 11/6/2026 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), in the 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: As an Oak Ridge Institute for Science and Education (ORISE) participant, you will join and learn from a community of scientists and researchers engaged in a regulatory science project examining how generic-to-generic switching and food effects contribute to variability in systemic opioid exposure under real-world conditions, using immediate-release (IR) oxycodone as the primary model system. Under the guidance of a mentor, you will have the opportunity to 1) characterize fed/fasted bioequivalence (BE) variability across approved IR opioid generics using Abbreviated New Drug Application (ANDA) data and identify products with borderline BE or differential food effects; 2) evaluate the clinical significance of observed variability in opioid-naive versus opioid-tolerant populations using literature-based exposure-response data; and 3) investigate biorelevant dissolution methods and an integrated risk-based framework to identify conditions

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where generic switching may amplify variability.

Findings will inform FDA regulatory science on BE evaluation approaches, product-specific guidance, and safe use of opioid generics. The project is led by the Office of Research and Standards (ORS) in the Office of Generic Drugs, CDER.

Learning Objectives: Under the guidance of your mentor, you will:

- Gain understanding of the principles of bioequivalence (BE) and food-effect assessment for IR opioid generic products using ANDA data.
- Learn how to analyze variability in systemic opioid exposure associated with fed and fasted conditions across approved IR opioid generics.
- Hone skills in identifying characteristics of generic products that demonstrate borderline bioequivalence or differential food effects.
- Gain understanding of literature-based exposure–response relationships relevant to opioid-naive and opioid-tolerant populations.
- Learn how to assess the potential clinical significance of variability in opioid exposure resulting from generic-to-generic switching.
- Develop skills in explaining factors that may contribute to variability in opioid absorption and systemic exposure under real-world conditions.
- Gain experience in applying concepts of biorelevant dissolution testing to evaluate formulation performance under physiologically relevant conditions.
- Learn how to develop integrated risk-based approaches for assessing variability associated with generic switching.
- Hone skills in regulatory science research, scientific literature evaluation, and data interpretation related to opioid product performance.
- Develop skills in communicating scientific findings related to bioequivalence, food effects, and formulation variability to multidisciplinary research audiences.

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

Anticipated Appointment Start Date: October 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;
- 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 doctoral degree (Ph.D., Pharm.D., or equivalent) in the one of the relevant fields (e.g. pharmaceutical sciences, pharmacokinetics/pharmacology, biopharmaceutics, biostatistics, or a closely related discipline).

Preferred Skills:

- Experience in drug absorption, bioequivalence (BE) principles, pharmacokinetic data analysis, and biostatistical methods
- Graduate training in dissolution science, formulation assessment, or quantitative/computational methods

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- Familiarity with biorelevant dissolution testing (e.g., fasted/fed state methods, two-stage dissolution)
- Experience in statistical or computational modeling, including biostatistical methods, PBPK, or population-based pharmacokinetic modeling
- Experience with biostatistical analysis relevant to BE studies, such as confidence interval estimation, mixed-effects models, or variability assessment
- Ability to conduct systematic literature reviews and integrate in vitro/in vivo data
- Strong scientific writing skills
- Motivation to participate independently and collaboratively in multidisciplinary settings

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (2 👁)
  - **Mathematics and Statistics** (11 👁)
  - **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.