Opportunity Title: FDA Global Generic Drug Regulatory Research Fellowship
Opportunity Reference Code: FDA-CDER-2026-0143

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

Reference Code FDA-CDER-2026-0143

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

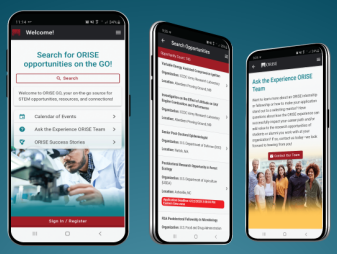
All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDER@orau.org. Please include the reference code for this opportunity in your email.

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Application Deadline 8/31/2027 12:00:00 AM 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: This educational research participation opportunity within FDA's Office of Generic Drugs (OGD) provides a mentored learning experience focused on the evolving global landscape of generic drug regulation, manufacturing, and supply chain dynamics. The research experience emphasizes comparative evaluation of international regulatory frameworks, bioequivalence approaches, and scientific considerations that may influence generic drug quality, access, development pathways, and approval timelines across jurisdictions. You will engage in interdisciplinary research and training activities related to regulatory science, including exploration of analytical chemistry, pharmacokinetics, manufacturing sciences, regulatory policy, and global harmonization concepts under the guidance of FDA scientists and subject matter experts. The opportunity also includes educational exposure to generic drug user fee program planning, workflow analysis, process documentation, and knowledge management approaches to strengthen understanding of how scientific and regulatory planning activities are developed, evaluated, and refined within a public health context.

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

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- Gain advanced knowledge of generic drug regulatory science, including international regulatory frameworks, bioequivalence recommendations, pharmaceutical manufacturing considerations, and global supply chain challenges that may influence generic medicine development, evaluation, and availability across jurisdictions.
- Develop interdisciplinary research competencies through mentored training activities involving scientific literature evaluation, comparative regulatory analysis, workflow and process mapping, technical documentation review, and examination of knowledge management approaches relevant to generic drug programs.
- Strengthen the ability to integrate scientific, regulatory, and policy perspectives through engagement with multidisciplinary subject matter experts in areas such as pharmacokinetics, analytical chemistry, manufacturing sciences, regulatory policy, and global harmonization.
- Gain educational research experience that supports academic and professional development in regulatory science, public health, health policy, program analysis, knowledge management, and related scientific or healthcare fields.

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

Anticipated Appointment Start Date: September 21, 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.

Qualifications

The qualified candidate should have received, or currently be pursuing, a bachelor's degree or higher in one of the relevant fields. Degree must have been received within the past five years.

Preferred Skills:

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- Ability to identify and analyze problems; weigh relevance and accuracy of information; generate alternative solutions; and make recommendations to research program.
- Experience assessing information/data related to drug products.
- Skills in verbal communications to present convey information related to a wide range of pharmaceutical issues, and effectively interact with colleagues of varying experience and skill levels.
- Ability to effectively communicate in varying writing formats to broad audiences of different experience and skill levels.

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 👁)
  - **Communications and Graphics Design** (3 👁)
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Engineering** (3 👁)
  - **Life Health and Medical Sciences** (22 👁)
  - **Mathematics and Statistics** (11 👁)
  - **Physics** (1 👁)
  - **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.)