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Opportunity Title: FDA Global Generic Drug Regulatory Research Fellow
Opportunity Reference Code: FDA-CDER-2026-0168

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

Reference Code FDA-CDER-2026-0168

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 10/9/2026 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), 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. These efforts cover more than just medicines.

Research Project: You will participate in a dynamic, internationally focused, educational research opportunity within FDA's Office of Generic Drugs (OGD) to advance FDA's gold standard approach to science-driven harmonization of generic drug regulation.

Under the guidance of a mentor, you will research emerging challenges in the global generic drug landscape, with a particular focus on the increasing complexity of the regulation and manufacture of generic drugs across global markets. You will have the opportunity to analyze how differing regulatory frameworks shape and respond to these developments, including their implications for drug quality, access, and approval timelines. Additionally, you will investigate global supply chain dynamics and how differences in regulatory frameworks and bioequivalence recommendations may impact the development and availability of generic medicines across jurisdictions.

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All activities undertaken by the Global Generic Drug Research Fellow directly advance OGD's regulatory science mission. By researching global supply chain dynamics and international regulatory frameworks, you will have the opportunity to generate insights that strengthen the scientific and regulatory understanding underpinning FDA's gold standard global harmonization, ultimately advancing public health objectives worldwide.

Learning Objectives: You will be mentored by senior FDA scientists, pharmacokineticists, chemists, and regulatory reviewers, and will learn to integrate perspectives from diverse scientific disciplines to build a comprehensive understanding of how different regulatory systems approach generic drug evaluation and harmonization.

Through this experience, you will develop an advanced understanding of global generic pharmaceutical regulatory science by engaging with regulatory scientists and policy experts from multiple national agencies, and will strengthen interdisciplinary competencies in areas such as analytical chemistry, pharmacokinetics, manufacturing sciences, and regulatory policy that are skills highly valued across the pharmaceutical and public health sectors.

Mentor: The mentor for this opportunity is Victoria Keck (victoria.keck@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 12 months 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 and Lawful Permanent Residents (LPR) only.

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

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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 bachelor's degree in the one of the relevant fields.

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's 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.