

**Opportunity Title:** FDA Product Specific Guidance and Research Fellowship

**Opportunity Reference Code:** FDA-CDER-2026-0014

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

**Reference Code** FDA-CDER-2026-0014

**How to Apply** *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!

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@oraui.org](mailto:ORISE_FDA_CDER@oraui.org). Please include the reference code for this opportunity in your email.

**Application Deadline** 12/31/2026 3:00:00 PM Eastern Time Zone

**Description** \*Applications will be reviewed on a rolling-basis.

**FDA Office and Location:** Research opportunities are available in the Office of Generic Drugs/Office of Research and Standards (ORS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) 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 part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than drug products and corresponding regulations. This project explores knowledge management systems for FDA-funded scientific research, CDER approved drug products, CDER published guidance including product-specific guidance (PSG), as well as the refinement of processes and infrastructure to analyze and track how research outcomes from FDA-funded scientific research can be used to support PSG development. This project includes the development of knowledge management and research management tools to maintain, monitor, and analyze how the impact of outcomes from a scientific research program can be maximized to support future decision making.

**Learning Objectives:** You will gain insight into the FDA's Office of Generic Drugs, and how their research supports guidance development and

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regulatory decision making as part of the Generic Drug User Fee Amendments (GDUFA) Program. Under the guidance of a mentor, you will be trained on aspects of developing and implementing knowledge management and research management systems and will utilize these systems as tools to monitor and manage scientific research that supports product specific guidance development and regulatory decision-making. This training will provide experience on the process by which product specific guidance is developed and tracked, which will teach skills to enable successful career transition into science and research in a regulatory environment.

**Mentor:** The mentor for this opportunity is Jasdeep Floura ([Jessie.Floura@fda.hhs.gov](mailto:Jessie.Floura@fda.hhs.gov)). If you have questions about the nature of the research, please contact the mentor.

**Anticipated Appointment Start Date:** March/April 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.

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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

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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, master's, or doctoral degree in one of the relevant fields.

**Point of Contact** [Ashley](#)

- Eligibility Requirements**
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
  - **Discipline(s):**
    - **Business** ([1](#))
    - **Chemistry and Materials Sciences** ([12](#))
    - **Communications and Graphics Design** ([2](#))
    - **Computer, Information, and Data Sciences** ([17](#))
    - **Engineering** ([1](#))
    - **Environmental and Marine Sciences** ([2](#))
    - **Life Health and Medical Sciences** ([51](#))
    - **Mathematics and Statistics** ([11](#))
    - **Physics** ([16](#))
    - **Science & Engineering-related** ([1](#))
    - **Social and Behavioral Sciences** ([30](#))

**Affirmation** 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.