

**Opportunity Title:** FDA Fellowship in Risk-Based Assessment & Inspections

**Opportunity Reference Code:** FDA-CDER-2024-1418

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

**Reference Code** FDA-CDER-2024-1418

**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@orau.org](mailto:ORISE.FDA.CDER@orau.org). Please include the reference code for this opportunity in your email.

**Application Deadline** 9/30/2024 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 in the Office of Strategic Programs/Office of Business Informatics, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) 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 work covers more than just medicines.

**Research Project:** In support of ensuring the availability of safe, effective, and high-quality drugs for the public, this project located in the Office of Strategic Programs/Office of Business Informatics will transform drug quality review and inspection management processes by infusing modern risk based regulatory approaches and tools in submission review, manufacturing facility assessment, and surveillance of marketed drugs and therapeutic biologics. This project is especially important due to the global nature of drug manufacturing and the sourcing of raw materials outside of the United States.

**Learning Objectives:** Under the guidance of a mentor, the participant will be trained on using critical decision support systems to provide global drug quality oversight and research. The participant will learn how to identify quality issues and evaluate the informatics quality platform by utilizing methods from the fields of computer science, decision science and operations research. This training is critical to our public health mission and will prepare the participant for a successful career transition into regulatory science research.

**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.



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**Level of Participation:** The appointment is full time.

**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 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. Degree must have been received within five years of

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the appointment start date.

Familiarity with data analytics is desired.

- Eligibility Requirements**
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
  - **Discipline(s):**
    - **Computer, Information, and Data Sciences** ([16](#) 👁)
    - **Life Health and Medical Sciences** ([45](#) 👁)

**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.