Opportunity Title: FDA Research Fellowship in Over-the-Counter Spray Drug Product
Opportunity Reference Code: FDA-CDER-2025-1469

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

Reference Code FDA-CDER-2025-1469

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. Please include the reference code for this opportunity in your email.

Application Deadline 3/31/2025 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 Division of Pharmaceutical Quality Research II (DPQR II), Office of Pharmaceutical Quality Research (OPQR), Office of Pharmaceutical Quality (OPQ), Food and Drug Administration (FDA) located in St. Louis, Missouri.

This is a collaborative research project in the Center for Drug Evaluation and Research (CDER). 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than just medicines.

Research Project: This research project will be part of larger effort examining the performance of topical spray devices. For over-the-counter (OTC) spray drug products, repeatable and consistent spray actuations are important for evaluating drug delivery performance. In this project, the participant will conduct research within a multi-disciplinary team to mimic human usage of the spray products and at the same time achieve the actuation consistency by ensuring precise control of important actuation parameters including force limit, position velocity, acceleration, and timing. The participant will engage with development of project specific protocol and methodology using the state-of-the-art spray actuation and characterization technologies, assisted by 3D printing, high speed imaging, modeling and simulation, etc., and use the newly developed methodology to examine a wide range of spray drug products. The resulting method developed through this project will provide a standardized scientific tool to evaluate the delivery performance of spray drug products.

Appointment Length: The appointment will initially be for eight months to

a 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.

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.

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Qualifications The qualified candidate should have received or be currently pursuing a doctoral degree in engineering and physical sciences. Qualified masters and bachelor's may also be considered provided that the candidate demonstrates strong analytical and research experience. Degree must have been received within the past five years or is anticipated to be received by 12/31/2025.

Point of Contact Sara Beth Hensley

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or anticipated to be received by 12/31/2025 12:00:00 AM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (5 👁)

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.)

I have read the FDA Ethics Requirements.