Opportunity Title: FDA Postdoctoral Fellowship - Biopredictive Dissolution Development for Oral Peptides
Opportunity Reference Code: FDA-CDER-2026-0125

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

Reference Code FDA-CDER-2026-0125

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 9/1/2026 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 within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at 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: Oral peptide drug products present unique scientific challenges because conventional quality control (QC) dissolution methods may not adequately capture the complex interplay among dosage form disintegration, peptide release, and gastrointestinal physiology that governs in vivo performance. The inclusion of permeability enhancers in products such as Wegovy further complicates the development of biopredictive dissolution methods. Such methods are important for informing bioequivalence assessments during lifecycle management - including bridging different products throughout development or implementing post-approval changes - and for supporting generic drug development.

This fellowship will provide training through participation in regulatory science research focused specifically on developing biopredictive

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dissolution methods for oral peptides. The goal is to unlock the potential of predictive biopharmaceutical tools that enable regulatory flexibility. The research outcomes will also support updates to dissolution guidance documents. Fellowship activities may include, but are not limited to:

1. Evaluating formulation and process variables that influence dissolution behavior;
2. Contributing to the development and assessment of discriminating and physiologically relevant dissolution methods;
3. Exploring relationships between in vitro dissolution behavior and in vivo absorption-relevant processes;
4. Applying advanced analytical approaches to characterize peptide release and performance;
5. Contributing to evidence generation that supports scientifically sound frameworks for biopredictive dissolution method development.

This opportunity aligns with the mission of U.S. Food and Drug Administration by advancing scientific tools needed to support evaluation of complex oral peptide products. Research in biopredictive dissolution can strengthen evidence-based approaches for assessing product performance, support generic drug development, and contribute to broader regulatory science efforts aimed at improving access to safe and effective medicines.

Learning Objectives: Under the guidance of senior scientist mentors, you will be engaged in pharmaceutics and regulatory science research, gaining hands-on experience in dissolution method development, analytical characterization, experimental design, and mechanistic interpretation of oral peptide performance. Your training will include exposure to advanced dissolution methodologies, principles aligned with ICH Q14 analytical development concepts, and approaches for linking in vitro data to the in vivo performance attributes. Additional educational opportunities include your participation in scientific seminars, interdisciplinary discussions, and collaborative research activities related to complex drug product evaluation.

Through this fellowship, you will develop an understanding of scientific factors governing dissolution and in vivo performance of oral peptide formulations, gain competency in development and evaluation of discriminating and biopredictive dissolution methods, and you will build familiarity with regulatory science considerations relevant to complex product performance assessment. You will also gain experience communicating research findings through technical reports, presentations, and potential publications, with progress supported through mentorship, research milestones, and scientific presentations.

The fellowship will provide you opportunities for interaction with multidisciplinary scientists in pharmaceutics, analytical chemistry, and regulatory science, as well as participation in scientific meetings, seminars, and collaborative research discussions. You may be a part of presentations and publications and gain professional experience relevant to careers in academia, industry, or government regulatory science.

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

Anticipated Appointment Start Date: September 1, 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.

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:

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- 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 doctoral degree in the one of the relevant fields.

Preferred skills/knowledge:

- Strong analytical capability.
- Pharmacy/pharmacology related knowledge is preferred.

Point of Contact

Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (2 👁)
  - **Engineering** (5 👁)
  - **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.