

Opportunity Title: FDA Stability Modeling of Biotechnology Products

Opportunity Reference Code: FDA-CDER-2025-1465

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

Reference Code FDA-CDER-2025-1465

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.

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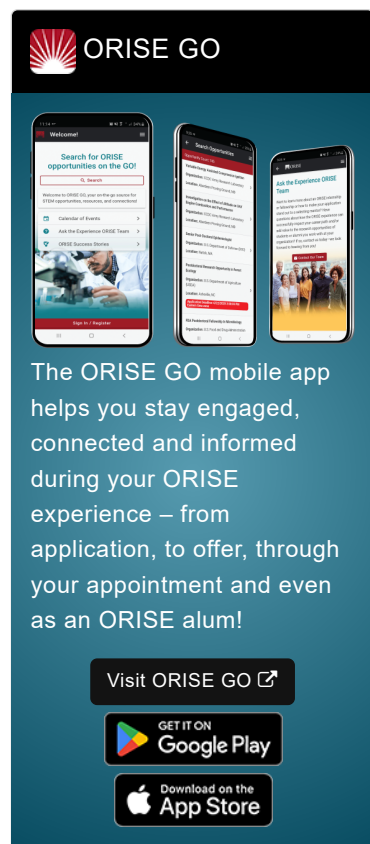
Application Deadline 1/31/2025 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), in the Office of Pharmaceutical Quality Research (OPQR), Office of Pharmaceutical Quality (OPQ) 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. This work covers more than just medicines.


Research Project: The requirement of 12 months of stability data is a rate-limiting factor for submission of biosimilar applications to the agency. Advanced kinetic modeling and extrapolation of stability data have been proposed to speed up the time to submission for protein drugs. This project will address the data required to adequately model protein drug stability by conducting both statistical and confirmatory experimental studies on stability of protein drugs. The protein drugs in accelerated and stress studies will be assessed alongside real-time stability samples for critical quality attributes to understand the kinetics of changes in stability indicating characteristics. The data will be used to assess modeling approaches for prediction of protein drug stability. A multi-disciplinary approach is critically




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needed to understand the impact of stability indicating characteristics of the protein drugs to kinetic models in order to understand their effect on stability modeling and make sound regulatory assessments.

Learning Objectives: Under the guidance of the mentor, the participant will be trained on advanced analytics to assess protein degradation. Activities may include orthogonal validation experiments utilizing specialized equipment such as chromatographic methods, mass spectrometry, and capillary electrophoresis to characterize the relationship between stability models and drug purity, potency and immunogenicity. The participant will also have the opportunity to participate in kinetic modeling of the data. This training will prepare the participant for a successful career transition into regulatory science research.

Anticipated Appointment Start Date: 2024/2025. 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.

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

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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 master's or doctoral degree in the one of the relevant fields (e.g. biology, biochemistry, biotechnology or related fields). Degree must have been received within the past five years, or anticipated to be received by 6/30/2025.

Preference is given towards doctoral degree students and graduates however qualified master's students and graduates will also be considered provided that the candidate demonstrates strong analytical experience.

Preferred skills:

- Experience with protein biology and/or biotechnology, and also have experience with analytics commonly used for analysis of protein structure including liquid chromatography, mass spectrometry, capillary electrophoresis sodium dodecyl sulfate (CE-SDS), and imaged capillary isoelectric focusing (iCIEF).
- Familiarity with kinetics modeling and use of R-based modeling packages, or similar platforms is ideal.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2025 12:00:00 AM.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** (2 )
 - **Life Health and Medical Sciences** (8 )
 - **Mathematics and Statistics** (1 )

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.)

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and

I have read the FDA Ethics Requirements.