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Opportunity Title: FDA Fellowship - Applied Regulatory Science In Vitro Molecular Assay Development
Opportunity Reference Code: FDA-CDER-2026-0116

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

Reference Code FDA-CDER-2026-0116

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 9/25/2026 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), Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS), located at White Oak, 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: You will contribute to testing therapeutic drug products, including small molecules of regulatory relevance to CDER, using in vitro techniques. The fellowship will also support the evaluation of novel approach methodologies (NAMs) and NAM-enabling technologies. This will include experimental design, testing and analysis of molecular changes associated with drug exposure, application of classical and advanced molecular biology techniques for gene expression and knockdown, cell isolation and culture, development and testing of cell-based models, data analysis, literature review, and manuscript preparation.

Learning Objectives: Under the guidance of an FDA mentor, you will:

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- Learn to evaluate therapeutic drug products using in vitro methods relevant to CDER regulatory review.
- Learn to design and conduct experiments supporting off-target safety assessment of small molecule therapeutics.
- Learn to develop and apply advanced laboratory techniques, SplintR-qPCR, and cell fractionation.
- Learn to develop NAMs enabling technologies and assess cell-based NAMs (NAMs).
- Learn to analyze experimental data and interpret findings to inform regulatory science.
- Learn to conduct literature reviews and prepare scientific manuscripts to support regulatory research dissemination.

Mentor: The mentor for this opportunity is Paula Hyland (paula.hyland@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: 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

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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 doctoral degree in one of the relevant fields (e.g. molecular biology, cell biology, genetics or genomics, biomedical sciences, pharmaceutical sciences, or a closely related discipline.). Degree must have been received within the past five years, or anticipated to be received by 8/30/2026.

Preferred skills:

- A strong background in molecular biology techniques, including DNA/RNA extraction, quantitative PCR (qPCR), and nucleic acid assay development and optimization (e.g., ligation-based assays).
- Experience with mammalian cell culture using 2D and/or 3D cell models and the design and execution of in vitro experiments.
- Experience characterizing cellular responses to drug treatment, with strong quantitative data analysis and interpretation skills

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 8/30/2026 12:00:00 AM.
- **Discipline(s):**
  - **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.)

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and
I have read the FDA Ethics Requirements.