Opportunity Title: FDA Fellowship in Development and Control of Cell Free Manufacturing Platform Technologies
Opportunity Reference Code: FDA-CDER-2026-0174

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

Reference Code FDA-CDER-2026-0174

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 3/31/2027 12:00:00 AM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available immediately with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) located 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 effort covers more than just medicines.

Research Project: Under the guidance of a mentor, you will engage in a hands-on learning experience involving Cell-free protein synthesis (CFPS) utilizing mammalian and prokaryotic extracts. This is a developing manufacturing technology that enables the rapid, decentralized, and on-demand production of life-saving therapeutics and medical countermeasures. However, the lack of standardized quality control assays and the inherent batch-to-batch variability of the biological raw materials pose significant regulatory challenges for broader implementation. Currently, there is a gap in establishing a robust Chemistry, Manufacturing, and Controls (CMC) framework to ensure the consistent quality of products derived from these diverse platforms. We propose to develop cell free manufacturing platform technology and validate robust analytical procedures to characterize the critical material attributes (CMAs) of both

mammalian (e.g., CHO, HeLa) and prokaryotic (e.g., E. coli) cell extracts to systematically assess their viability and reproducibility for safe and effective biomanufacturing.

Research Initiatives: Improve or advance science-based quality standards and manufacturing practices to assure product quality, safety, and efficacy & identify, evaluate, and understand emerging product, manufacturing, and analytical testing technologies to aid in risk-based quality assessment and support standards, policy and guidance development.

Research Activities: Under the guidance of a mentor, you will have the opportunity to participate in the following activities:

- Execution of mammalian and prokaryotic cell-free protein synthesis reactions, actively developing and qualifying analytical assays (e.g., fluorometric assays, HPLC, ceSDS) to monitor extract productivity, batch-to-batch variability, and overall protein quality.
- Weekly meetings with mentor to assess progress and provide targeted training, review experimental data, and discuss how the data applies to current CMC regulatory frameworks.
- Training on how to deliver research findings to a scientific audience by presenting at internal FDA meetings and actively participating in the drafting of a manuscript for a peer-reviewed scientific journal.
- Biweekly meetings to learn scientific knowledge in a variety of disciplines.

Learning Objectives: You will gain and advance your current scientific skill set in cutting-edge biomanufacturing and analytical characterization. Additionally, you will learn how to interpret complex scientific data, perform advanced laboratory techniques, and apply ICH guidelines to experimental design. You will also learn how to communicate research findings effectively, bridging the gap between bench science and regulatory policy. Your training and acquired skill set will have applicability across scientific disciplines to ensure you have the opportunity to choose different career paths in academia, industry, or the federal government.

During this appointment, you will:

- Receive hands-on training in advanced analytical techniques and cell-free biomanufacturing workflows (spanning both prokaryotic and mammalian systems) to advance your technical skillset.
- Improve scientific knowledge regarding FDA regulatory science, Quality by Design (QbD), and CMC requirements.
- Learn about laboratory-scale extract production, qualification, and protein synthesis.
- Improve scientific communication during presentation construction and the delivery of research findings to a regulatory audience.
- Learn presentation skills and training in scientific manuscript drafting.
- Support your scientific career pursuit by attending weekly meetings with a group of seasoned scientists, at which they you will present your research and integrate your findings into a variety of scientific and

regulatory disciplines.

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

Anticipated Appointment Start Date: October 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 only.

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;

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- 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. Degree must have been received within the past five years.

Preferred skills:

- Hands-on experience with cell-free protein synthesis (CFPS) platforms and protocols.
- Familiarity with recombinant protein engineering and biomanufacturing scale-up.
- Experience analyzing protein aggregation dynamics and nuclease activity (e.g., DNase, RNase, micrococcal nuclease).
- Experience in standard protein purification and analytical assays.

Point of Contact

Ashley

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Engineering** (3 👁)
  - **Life Health and Medical Sciences** (6 👁)

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.