Opportunity Title: FDA Fellowship - Rapid Sterility Testing Innovation: Evaluating ATP-Bioluminescence Technology for Regulatory Science Applications
Opportunity Reference Code: FDA-CDER-2026-0084

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

Reference Code FDA-CDER-2026-0084

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.

Application Deadline 6/30/2026 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 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: The participant will engage in a research initiative aiming to improve the Agency's understanding of ATP-bioluminescence technology, which has been identified as a rapid microbial method that aligns with current pharmaceutical industry trends, to better support submissions utilizing this approach. Researching collaboratively with FDA scientists, the participant will cultivate and maintain approximately 10-12 biosafety level 1 and level 2 bacteria species that will be subject to the novel ATP-bioluminescence testing methods. The participant will inoculate relevant biomanufacturing process fluids with bacteria species to determine potential matrix interference and assay limitations. Results from this study will be reported to the cross-center Rapid Sterility Testing WG. Findings can be used in support of regulatory risk-based assessments and provide scientific basis for guidance on the use of commercially available ATP-bioluminescence detection system for microbial testing of biologic products.

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Learning Objectives: The fellowship will provide you structured training in applied regulatory science, linking process understanding of novel manufacturing technologies to evolving regulatory expectations. You will gain experience in hands-on microbiological research, performing quantitative colony counting, ATP-bioluminescence data analysis with respective commercial software, and understanding the impact of biomanufacturing process buffers on microbiological recovery and detection. Your training will also cover regulatory science principles relevant to other adventitious agent testing. Learning outcomes include:

- Upon completion, you will gain proficiency in USP microbiological laboratory research as well as a thorough understanding of the regulatory requirements for sterility and bioburden testing.
- You will develop expertise in Biosafety Level 1 and Level 2 cell handling, sterility testing, bioburden testing, and novel ATP-bioluminescence technologies.

This fellowship will strengthen your scientific and regulatory knowledge of microbiological science and adventitious agent safety for both pharmaceuticals and therapeutic proteins, offering opportunities for collaboration with FDA scientists, contributions to peer-reviewed publications, external and internal presentations, and involvement in a cross-center initiative to understand novel technologies.

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

Anticipated Appointment Start Date: May/June 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:

- 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 Applicants should have received or be currently pursuing a master's or doctoral degree in one of the relevant fields. Degree must have been earned within the past three years or be expected to receive by June 30, 2026.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 36 months or anticipated to be received by 6/30/2026 11:59:00 PM.
- **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.