Opportunity Title: FDA High-resolution Analytics Fellowship for Oligonucleotide Therapeutics
Opportunity Reference Code: FDA-CDER-2026-0078

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

Reference Code FDA-CDER-2026-0078

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 5/31/2026 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 St. Louis, Missouri.

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: This project is located in the Division of Pharmaceutical Quality Research II (DPQR II), Office of Pharmaceutical Quality Research (OPQR), Office of Pharmaceutical Quality (OPQ). It will concentrate on the emerging class of synthetic oligonucleotide therapeutics presents distinct regulatory hurdles, largely stemming from their molecular complexity. This complexity arises from diverse chemical modifications aimed at enhancing the stability, efficacy, and safety of these products. Consequently, there is a pressing need to enhance the resolution of conventional analytical methods, such as LC-UV and LC-UV/MS, to meet the escalating analytical demands. Robust and sensitive analytics leveraging modern technologies are imperative to advance both the development and regulation of oligonucleotide drugs.

Learning Objectives: Under the guidance of the mentor, you will receive instructions on utilizing chromatography, mass spectrometry, and other

modern analytical techniques to perform structural characterization of oligonucleotides. You will learn to employ a higher-dimensional analytical platform for analyzing complex molecules. Laboratory activities will entail executing experimental designs, conducting laboratory analyses to help develop analytical methods comprehensively, and gaining insight into drug development and product quality control. Additionally, you will participate in data evaluation and documentation, collaborating with their mentor on publications, presentations, or reports to learn effective communication of regulatory science to both the Agency and industry stakeholders.

Mentor: The mentor for this opportunity is Kui Yang (Kui.Yang@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

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

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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 have received a doctoral degree in one of the relevant fields (physical sciences, preferably analytical chemistry field).

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (4 👁)
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Life Health and Medical Sciences** (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.)
and
I have read the FDA Ethics Requirements.