Opportunity Title: FDA Drug Quality Fellowship
Opportunity Reference Code: FDA-CDER-2022-1182

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

Reference Code FDA-CDER-2022-1182

How to 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 12/31/2022 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Office of Pharmaceutical Quality / Office of Testing and Research, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in St. Louis, Missouri.

Synthetic oligonucleotide therapeutics (ONTs) have the potential of regulating proteins considered “undruggable" by small molecules, but pose unique regulatory challenges as existing guidelines are not sufficient for this evolving class. This gap is largely attributed to the molecular complexity arising from a variety of chemical modifications introduced to improve the stability, efficacy and safety of ONTs. This problem reinforces the need to improve the resolution of conventional methods such as LC-UV and LC-UV/MS to address the increasing analytical challenges faced by ONTs. Robust and sensitive analytics using modern technologies are demanded to promote ONT drug development and regulation.

The participant will be instructed to use chromatography and mass spectrometry as well as other modern analytical techniques to conduct structural characterization of oligonucleotides and in-depth profiling of product-related impurities. The participant will learn to implement a higher-dimensional analytical platform for next generation complex molecule analysis. Participant laboratory activities will include execution of experimental designs, and laboratory analysis to fully develop analytical methods and understand drug development and product quality control. The participant will engage in data evaluation and documentation (publication, presentation or report) with their mentor to learn how to communicate regulatory science to FDA and industry stakeholders.

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 initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the St. Louis, Missouri, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

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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 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 or be currently pursuing a doctoral degree with completion by December 31, 2022. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Familiarity with the latest liquid chromatographic and mass spectrometric (MS) techniques and application of those techniques to characterization and quantitative analysis
- Analytical method development for complex matrices
- Knowledge of oligonucleotides and ion mobility MS technique

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 12/31/2022 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (5 👁)
  - **Life Health and Medical Sciences** (3 👁)

Affirmation

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.)