Opportunity Title: FDA Analysis of Aerosol Spray Drug Products Fellowship
Opportunity Reference Code: FDA-CDER-2022-0758

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

Reference Code FDA-CDER-2022-0758

How to Apply ***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!

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 5/31/2022 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available in the Office of Pharmaceutical Quality/ Office of Testing and Research (OTR) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in St. Louis, Missouri. 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

The project aims to better understand the physical properties of aerosol spray drug products by examining the characteristics of aerosol spray products, including formulation and performance. Analysis will focus on aerosols emitted after actuation from the aerosol spray cannisters, including particle size distribution, droplet evaporation, movement, and deposition. New methodology and data will be generated on the performance of aerosol sprays to support FDA regulatory research and activities.

Under the guidance of the mentor, the participant will develop aerosol/particle analytical methods to support regulatory activities. The participant will also learn to characterize physical characteristics of aerosol spray products using instrumentation such as laser diffraction, aerodynamic/scanning mobility particle sizers, cascade impactors, HPLC/MS, etc. and conduct product drug performance evaluations on characteristics critical for drug quality.

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 a doctoral degree in one of the relevant fields, or be currently pursuing the degree with completion by the end of May 2022. Degree must have been received within the past five years.

Preferred skills/ knowledge:

- Knowledge with evaluating inhalation products (metered dose inhalers, dry powder inhalers) or aerosol cannisters.
- Knowledge in aerosol modeling and simulation.
- Modeling and simulation experience knowledge with software such as COMSOL Multiphysics.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 5/31/2022 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (3 👁)
  - **Engineering** (5 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Physics** (1 👁)

Affirmation

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)