Opportunity Title: FDA Modeling of Dry Powder Inhaler (DPI) Drug Delivery
Opportunity Reference Code: FDA-CDER-2021-0700

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

Reference Code FDA-CDER-2021-0700

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 12/31/2021 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 Generic Drugs/ Office of Research and Standards (ORS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

Current product-specific guidance recommendations for demonstrating bioequivalence (BE) of potential generic dry powder inhalers (DPIs) use a weight-of-evidence approach that includes in vitro tests such as aerodynamic particle size distribution and single actuation content, as well as in vivo studies such as a pharmacokinetic study and a pharmacodynamic (PD) or a comparative clinical endpoint (CCEP) study. However, PD/CCEP studies may be prohibitive due to the expected need for large numbers of subjects. A greater understanding of aerosol behavior is needed to consider BE approaches that may not include recommendations for PD/CCEP studies. Computational fluid dynamics (CFD) and discrete element method modeling (DEM) may be used to increase understanding.

Under the guidance of the mentor, the participant will gain knowledge of DEM modeling and be provided with the means to integrate DEM modeling with CFD. The participant will also learn how DPI systems work and how CFD-DEM modeling may be used to increase understanding of these systems. The participant will learn about pharmaceutical drug development and regulation, and the participant will be given opportunities to publish results.

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 Silver Spring, Maryland, 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 be currently pursuing or have received a doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students or Postdoctoral.
- **Discipline(s):**
  - **Engineering** (2 👁)
  - **Mathematics and Statistics** (10 👁)

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.)