Opportunity Title: FDA Uniformity of Dosage Units (UDU) Fellowship
Opportunity Reference Code: FDA-CDER-2021-0726

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

Reference Code FDA-CDER-2021-0726

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 Pharmaceutical Quality/ Office of Pharmaceutical Manufacturing Assessment (OPMA), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. 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.

Uniformity of dosage units (UDU) in a manufactured batch is one of the most critical quality attributes for solid oral dosage forms (IR, ER, tablets and capsules). FDA has not issued guidance to replace the withdrawn draft guidance since 2013. A large variety of BU/CU (blend uniformity/content uniformity) evaluation methodologies (e.g., sampling plans, testing protocols, acceptance criteria), mostly based on literature, can be found in submissions. Currently, OPMA assessors conduct BU/CU evaluations with uncertain levels of inconsistency which may bring confusion to the applications.

Under the guidance of the mentor, the participant will gain an understanding of the industry's application of historical guidance/literature proposals in BU/CU of solid oral dosage forms; categorize various approaches/methods; identify potential risks to drug quality for each category, focusing on the inappropriate approaches/methods. The participant will also gain an understanding of how OPMA (OPQ) assessors review these proposals/methods; and check the consistency on risk assessment (initial and final) and typical BU/CU requirements for development, PPQ and commercial stages. The participant will be able to achieve consensus amongst OPMA assessors in risk assessment and decision-making on approvability of UDU testing proposals.

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

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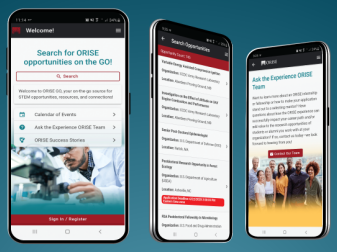

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renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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.

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 bachelor's, master's or doctoral degree in one of the relevant fields. Degree must have been received within the last five years.

Preferred knowledge/skills:

- Strong statistical and data mining knowledge
- Ability to do independent research
- Skills in SAS or MATLAB
- Familiarity with pharmaceutical solid oral dosage formulation and manufacturing

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students, Post-Bachelor's, Postdoctoral, Post-Master's, or Undergraduate Students.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (1 👁)
  - **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.)