Opportunity Title: FDA Drug-Device Combination Products and Human Factors Fellowship
Opportunity Reference Code: FDA-CDER-2023-1289

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

Reference Code FDA-CDER-2023-1289

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 9/30/2023 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 Research and Standards (ORS), Office of Generic Drugs (OGD) within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) located 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.

This research project relates to development of scientific methods and data to support development of generic drug-device combination products and substitution of these products for their reference listed drug (usually the brand name innovator product). The research outcomes will help FDA and the generic drug industry better understand the relationship between the device user interface design differences and user errors and how this relationship is influence by clinical use environment (setting of use) and indicated user populations.

Under the guidance of the mentor, the participant will gain a comprehensive understanding of the scientific and regulatory challenges that must be considered when assessing the user interface of complex generic combination drug-device products with device components that may have multiple levels of complexity.

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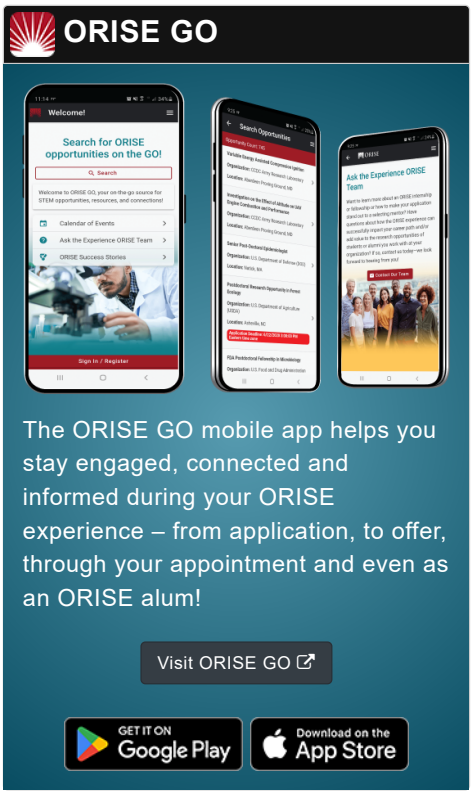

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The participant will:

- Investigate and analyze how device constituent parts are described in pre-existing guidance and standards and use this information to guide development of standardized language for similar classes of devices that may be submitted under abbreviated new drug applications (ANDAs) and NDAs.
- Identify standardized techniques that may be useful in identifying and characterizing differences in device constituent parts between test products and respective reference products.
- Collaborate with cross-disciplinary teams across Divisions and Offices within the Center to present research outcomes and contribute findings to work groups and databases that support office-wide activities.
- Investigate the end-user and use environment of generic drug-device combination products and understand how this may impact the potential substitutability of a proposed generic drug-device combination product.

The participant will gain insight into the FDA's Office of Generic Drugs and how their research supports guidance development and regulatory decision making, as part of the Generic Drug User Fee Amendments (GDUFA) Program.

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.

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 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.

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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 master's or doctoral degree in one of the relevant fields, or be currently pursuing one of the degrees with completion before September 30, 2023. Degree must have been received within five years of the appointment start date.

Preferred skills / knowledge:

- Drug development research or pharmaceutical industry knowledge
- Familiarity with drug-device combination products, medical devices, human factors, engineering.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 9/30/2023 12:00:00 AM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (48 👁)

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.)

I have read the FDA Ethics Requirements.