

Opportunity Title: FDA Drug-Device Combination and BTB Products Fellowship

Opportunity Reference Code: FDA-CDER-2022-0797

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

Reference Code FDA-CDER-2022-0797

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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@oraui.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 (OPQ)/ Office of New Drug Products (ONDP) at the 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.

This project will consist of collecting quality data to identify challenges and gaps faced during the product development and marketing applications in the following two areas: breakthrough therapy designated (BTD) drugs and drug-device combination products.

Under the guidance of the mentor, the participant will learn the current laws, regulations, policy, and guidance related to different types of drug applications from a unique chemistry, manufacturing and controls (CMC) perspective. The participant will be trained on FDA databases and will learn the basics of the FDA drug evaluation process for new drug applications (Quality/CMC sections). The participant will also gain knowledge in data mining, database creation, and an understanding of drug development (Quality/CMC) challenges.

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



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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 master's or doctoral degree (preferred) in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred Skills:

- Strong analytical experience
- Knowledge with Microsoft access
- Programming skills
- Knowledge in chemistry

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** ([1](#) )
 - **Computer, Information, and Data Sciences** ([1](#) )
 - **Engineering** ([1](#) )
 - **Life Health and Medical Sciences** ([48](#) )

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.)