

Opportunity Title: FDA Global Manufacturing Fellowship

Opportunity Reference Code: FDA-CDER-2021-0622

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

Reference Code FDA-CDER-2021-0622

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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@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 8/31/2021 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.

The Center for Drug Evaluation and Research (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 U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

This project is to conduct analysis of global manufacturing sites for all applications containing complex drug products, with a focus on generic products. The outcome of this study will provide a clear picture of complex generic product manufacturing sites and capability distribution to enhance FDA's oversight on these global facilities.

Under the guidance of the mentor, the participant will learn FDA approval processes of drug products and drug product manufacturing facilities, database management, and collaboration with cross-disciplinary teams.

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



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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 five years of the appointment start date.

Preferred skills:

- Strong background in written and oral communication
- Publication history in peer reviewed journals
- Previous knowledge with database management and analytics

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Computer, Information, and Data Sciences** (17 👁)
 - **Engineering** (1 👁)
 - **Life Health and Medical Sciences** (4 👁)
 - **Mathematics and Statistics** (1 👁)
 - **Social and Behavioral Sciences** (1 👁)