Opportunity Title: FDA Manufacturing Related Deficiencies Assessment Fellowship
Opportunity Reference Code: FDA-CDER-2021-0668

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

Reference Code FDA-CDER-2021-0668

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.**

Two research opportunities are 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) located in Silver Spring, Maryland.

In the United States, generic drugs constitute about 90% of prescriptions filled; however, the approval rate of Abbreviated New Drug Applications (ANDA) is generally low, especially for the first assessment cycle. Less than 16% of the ANDAs were approved during the first assessment cycle for fiscal year 2018. In the same year, 4452 information requests and 2648 complete responses were issued by the FDA to the generic applicants; though, it is not clear how many of these deficiencies originated in the manufacturing (including facilities) sections of ANDAs.

Throughout the course of this research project the participant(s) will learn to collect and analyze manufacturing related deficiencies which may be responsible for the low first cycle approval rate of ANDA applications. This fellowship will provide the participant(s) with the opportunity to acquire a keen understanding of regulatory sciences that supports the development of generic pharmaceuticals.

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 six months, 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 part-time (20 hours per week) 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

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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:

- Knowledge in Microsoft Excel

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)