**Opportunity Title:** FDA Fellowship in the Analysis of ANDA Submission Trends and Workload Distribution
**Opportunity Reference Code:** FDA-CDER-2023-1225

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

**Reference Code** FDA-CDER-2023-1225

**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** 3/31/2023 3:00:00 PM Eastern Time Zone

**Description**

***Applications will be reviewed on a rolling-basis.**

**CDER Office/Lab and Location**: A research opportunity is available in the Office of Program and Regulatory Operations (OPRO), Office of Pharmaceutical Quality (OPQ). Food and Drug Administration (FDA) located in Silver Spring, Maryland. This is a collaborative research project in the Center for Drug Evaluation and Research (CDER). 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 research covers more than just medicines.

**Research Project:** This project seeks to examine and better predict appropriate resources and expertise needed to support industry. The research will focus on mining and analysis of historical and current data trends in relation to required disciplines.

Under the guidance of the mentor, the participant will learn about drug application submission and product types, identifying historical and current trends. The participant will research existing publications on workload analytics and algorithm use when the level of effort of work varies from one resource to the next and when resource levels are not equal. This research will allow the participant(s) to develop proof-of-concept proposals for inclusion in projects with the use of data mining and predictive analytics. Additionally, participant(s) will learn all the technical components of drug applications and the assessment process.

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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

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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 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 in one of the relevant fields. Degree must have been received within the past five years.

Experience in VBA coding algorithms and strong analytical skills is preferred.

**Eligibility Requirements**

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 12/31/2023 11:59:00 PM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Mathematics and Statistics** (11 👁)

**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.)