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Opportunity Title: FDA- CDER Data Management of Drug Product Manufacturing Equipment
Opportunity Reference Code: FDA-CDER-2024-1366

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

Reference Code FDA-CDER-2024-1366

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 3/31/2024 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 Pharmaceutical Manufacturing Assessment (OPMA), Office of Pharmaceutical Quality (OPQ). The Office of Pharmaceutical Manufacturing Assessment (OPMA) evaluates drug product manufacturing process including the risk of presence of Process Equipment Related Leachables (PERL) in the drug product within the Food and Drug Administration (FDA) located 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than just medicines.

Research Project: The project involves manufacturing condition information and assessment outcomes of the equipment are not easily accessible, analyzed, and cross-referenced. The aim of the project is to establish a searchable database that collates manufacturing equipment with mitigated PERL risks and the relevant manufacturing conditions. The database will be used to assist risk-based assessment of drug product manufacturing process and improve assessment consistency.

Under the guidance of the mentor, the participant will learn the concept, principles, and regulations underlying quality assessment of drug product manufacturing process, especially those related to Process Equipment Related Leachables (PERL). The participant will also learn data and knowledge management enabling quality assessment using all available knowledge. This research will allow the participant to develop proof-of-concept proposals for the use of data mining and predictive analytics to aid risk-based manufacturing equipment assessment.

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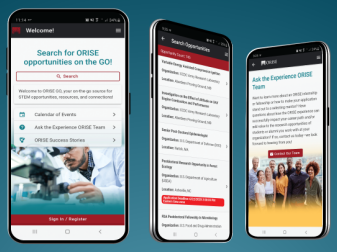
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This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The appointment is for 12 months. 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.

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 doctoral degree in one of the relevant fields (Pharmaceutical Science, Chemical Engineering, or Chemistry), or be currently pursuing a doctoral degree with completion before March 29, 2024. Top candidates will have demonstrated experiences in pharmaceutical development, formulation, or drug product manufacturing process development. Proficiency in Python, R, or other programming languages for data analysis is highly desired. Qualified masters may also be considered provided that the candidate demonstrates strong relevant experience. Degree must have been received within five years of the appointment start date.

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Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Engineering** (2 👁)

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.)

and

I have read the FDA Ethics Requirements.