Opportunity Title: FDA Fellowship on Impacts of Cell Substrate on Product Quality Attributes
Opportunity Reference Code: FDA-CDER-2023-1290A

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

Reference Code FDA-CDER-2023-1290A

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 12/29/2023 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 Biotechnology Products (OBP), Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. When a drug manufacturer of a biotechnology product changes the expression system (cell substrate) used to generate the protein therapeutic, it is considered a high-risk manufacturing change that may impact critical drug product quality attributes, such as protein structure, potency, and/or impurity profiles, which in turn may or may not impact pharmacokinetics (PK), pharmacodynamics (PD), clinical safety and/or efficacy. The goal of this project is to create a database of the characterization data provided before and after a cell substrate manufacturing change to analyze and identify potential correlations between cell substrate and specific critical quality attributes (CQAs) of the product. This database and subsequent exploratory data analysis will be critical tools for assessors when reviewing submissions involving cell substrate manufacturing process changes and biosimilars. Furthermore, the data will be used to identify knowledge gaps that can be addressed in laboratory-based research projects within our office.

Under the guidance of a mentor, the participant will learn how to navigate the Electronic Common Technical Document (eCTD) format used for submitting applications, amendments, supplements, and reports to FDA's Center for Drug Evaluation and Research (CDER). The participant will help create a database of cell substrate manufacturing changes that have occurred in OBP products and learn to perform correlational analysis of analytical characterization data to study the relationship between cell substrate and product quality attributes. The participant will also have the opportunity to train on laboratory equipment within the upstream

bioprocessing laboratory, including several bioreactor systems, if desired.

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 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 bachelor's degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Knowledge in the following:
  - data mining and/or database generation

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- statistical (e.g., JMP) and multivariate data analysis software (e.g., SIMCA) used for large dataset analyses
- statistics and multivariate data analysis (MVDA), including exploratory data analysis and predictive modeling
- fundamental biochemistry and protein structure and function
- fundamental protein purification and analytical techniques and concepts, such as liquid chromatography and spectroscopy
- mammalian cell culture and aseptic technique
- biomanufacturing operations

- Familiarity with developing software solutions in Python and/or MATLAB, as well as data processing and analysis libraries, such as NumPy, Pandas and Matplotlib
- Experience with statistical modeling and machine learning techniques, such as regression analysis, clustering, and classification

Eligibility Requirements

- **Degree:** Bachelor's Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (1 👁)

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). I have read the FDA Ethics Requirements.