Opportunity Title: FDA Bioprocessing Lab Fellowship
Opportunity Reference Code: FDA-CDER-2020-0585

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

Reference Code FDA-CDER-2020-0585

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 3/31/2021 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 Pharmaceutical Quality/Office of Biotechnology Products (OBP), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

This research project leverages state-of-the-art instrumentation for production of a therapeutic protein with real-time bioreactor sampling, protein purification, and drug substance characterization including large molecule critical quality attribute (CQA) analysis. OBP has the capacity to grow six 5L parallel bioreactors with in depth monitoring of nutrient and waste levels in real-time, cell viability and growth rates, cell respiration, and osmolarity. Basic parameters such as pH and dissolved oxygen are also monitored, and the system has the capacity for near at-line sterile auto-sampling of the six 5L vessels. OBP develops and performs sequential single- and multi-column chromatographic separation methods to optimize purification for different products. OBP models commercial upstream and downstream unit processes to advance risk evaluation and mitigation in continuous manufacturing. OBP has also developed purification chromatography and other process analytical technologies (PAT) that can simultaneously purify antibodies from raw cell culture harvest or purification samples as well as test CQAs like stability and aggregation state. The goal is to integrate these elements into the model production train for real-time therapeutic protein analysis (e.g. glycoforms, product titer, aggregation state, charge profile).

Under the guidance of a mentor, the participant may be involved in the following activities:

- Researching a new model bioprocess system and commercially available PAT tools, engineering runs with a variety of production platforms.
- Helping develop and understand DoE methodology to adjust relative culture conditions of known metabolic factors of glycosylation and/or predict stability factors in drug product formulation development.
- Exploring Failure Mode and Effects Analysis (FMEA) during product and process development research.
- Training and exploration of new bioprocessing/analytical equipment including: High performance liquid chromatography, mass spectrometry (Q and QQQ), automated liquid drug formulation analyzer, flow-imaging microscope/ RAMAN spectroscope, UV-vis and variable pathlength spectroscope, modular perfusion-capable micro bioreactors.
- Understanding bioprocessing relevant adventitious microbial agents, including inactivation and clearance studies.

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

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employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

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, master's, or doctoral degree in one of the relevant fields, or be currently pursuing a master's or doctoral degree. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Knowledge in analytical chemistry involving biologic/protein drug molecules, including High Performance Liquid Chromatography, Capillary Electrophoresis (or micro-capillary), LC/Mass Spectrometry (QDA/QToF/ QQQ), dynamic light scattering and other particle sizing techniques
- Knowledge in mammalian cell culture techniques for CHO cells including spinner flasks, lab-scale bioreactors, aseptic technique, cell counting, biolayer interferometry, and upstream bioprocessing
- Knowledge in preparative chromatography/protein separations using Fast Protein Liquid Chromatography systems, protein characterization with Differential Scanning Fluorimetry/Isothermal Chemical Denaturation, Ultrafiltration/Diafiltration, DNA extractions/PCR, microbial enumeration/bioburden testing, and downstream processing

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (2 👁)
  - **Engineering** (2 👁)
  - **Life Health and Medical Sciences** (4 👁)

Affirmation

I have received a bachelor's, master's, or doctoral degree or am currently pursuing a master's or doctoral degree.