Opportunity Title: FDA Therapeutic Proteins Fellowship
Opportunity Reference Code: FDA-ORA-2020-0005

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

Reference Code FDA-ORA-2020-0005

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.OC.other@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 1/1/2021 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available at the U.S. Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Northeast Medical Products Laboratory located in Jamaica, New York.

In this project, the participant will be involved in research on both the development of analytical methods to characterize protein glycans, and the evaluation of glycan critical quality attribute (CQA) variations of different brands of protein drug products currently available in US market. Under the guidance of a mentor, the participant will be trained in the following activities:

- Establish protocols for the characterization of terminal sialic acid residues in both monosaccharide and glycopeptide level
- Establish protocols for the characterization of critical glycan epitopes such as alpha-Gal and N-glycolyl neuraminic acid
- Elucidate complex glycan structure by mass spectrometry
- Quantify or profile N- and/or O- linked glycans by chromatography, mass spectrometry or NMR

The Pharmaceutical Analytical Group has been developed in Northeast Regional Laboratory to support the regulatory needs of Office of Regulatory Science (ORS) and Center for Drug Evaluation (CDER) scientists in the area of evaluation of protein-based pharmaceuticals (nano-scale) for therapeutic safety and efficacy to safeguard patient health and wellness. This group is formed to support ORA in developing and executing NMR-based analytical methods to qualify complex drugs.

Anticipated Appointment Start Date: December 2020

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

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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 Jamaica, New York, 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 have received a master's or doctoral degree in one of the relevant fields, or be currently pursuing one of the degrees and will reach completion by the appointment start date. Degree must have been received within five years of the appointment start date.

Preferred skills:

- General knowledge of chromatography and mass spectrometry
- Experience in enzymatic digestion and protein sample preparation/handling
- Experience in peptide mapping, glycan characterization and related software database searching
- Experience in complex glycan structure elucidation with mass spectrometry and/or glycanase treatment
- Experience with conducting large molecule characterization and conformance analysis using mass spectrometry or NMR

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 12/15/2020 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (6 👁)
  - **Communications and Graphics Design** (2 👁)
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Life Health and Medical Sciences** (2 👁)
  - **Mathematics and Statistics** (10 👁)
  - **Physics** (1 👁)