Opportunity Title: FDA Model-Informed Drug Development Approaches for Evaluation of Therapeutic Proteins and Peptides
Opportunity Reference Code: FDA-CBER-2020-0015

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

Reference Code FDA-CBER-2020-0015

How to Apply 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. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CBER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 12/31/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available in the Office of Tissues and Advanced Therapies (OTAT), at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project will develop and facilitate the application of model-informed drug development (MIDD) tools for the elucidation of pharmacokinetics (PK), pharmacodynamics (PD) and immunogenicity of therapeutic products. Under the guidance of a mentor, the selected participant will leverage multiple data sources and contribute to the development of quantitative models by incorporation of mechanistic knowledge, developmental maturation and unique features of macromolecules across the pediatric age groups.

Through this research opportunity, the selected participant will have the opportunity to learn and apply computational modeling skills, including PK/PD modeling, physiologically-based pharmacokinetic modeling and quantitative system pharmacology modeling, to address public health-related issues and gain experience in developing tools geared towards the advancement of regulatory science. During the project, the participant will be actively encouraged to present the research at internal and external meetings and publish the findings in peer-reviewed journals. The training will be useful for individuals seeking careers in both academia and industry.

Anticipated Appointment Start Date: September 1, 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 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

Opportunity Title: FDA Model-Informed Drug Development Approaches for Evaluation of Therapeutic Proteins and Peptides
Opportunity Reference Code: FDA-CBER-2020-0015

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 five years of the appointment start date.

Preferred skills:

- Analytical skills
- Experience in modeling and simulation software (e.g. R, Matlab, NONMEM, etc.)

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Engineering** (2 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)