Opportunity Title: FDA Postdoctoral Fellowship in Computational Modeling
Opportunity Reference Code: FDA-NCTR-2021-0014

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

Reference Code FDA-NCTR-2021-0014

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

Application Deadline 8/31/2021 3:00:00 PM Eastern Time Zone

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

A postdoctoral fellowship opportunity is currently available in the Division of Biochemical Toxicology, National Center for Toxicological Research (NCTR) of the U.S. Food and Drug Administration (FDA) Jefferson Laboratories Campus located in Jefferson, Arkansas.

Research efforts will include participation in multi-disciplinary efforts in a nationally recognized training program in support of the FDA's mission and be trained to conduct fundamental and applied research designed to elucidate mechanisms of toxicity and support risk-assessment for chemicals of interest to the FDA. The selected participant will be trained under Dr. Annie Lumen and her team on the development and use of pharmacokinetic and mechanistic models on projects in support of NCTR's objectives and the FDA mission. Opportunities may include developing PBPK models for underrepresented life-stages to investigate and ensure the safety and efficacy of drugs repurposed for SARS-CoV-2 infection, characterizing life-stage specific variabilities to derive intra-population extrapolation strategies, and simulating drug-drug interactions of medications used concomitantly for treating COVID-19 which may differ from typical clinical trial participants based on specific life-stages. Through this fellowship, the selected participant will have the opportunity to learn and apply computational modeling skills, including life-stage PBPK modeling, local and global sensitivity analysis and population analysis, to address public health-related issues and gain experience in developing tools geared towards the advancement of regulatory science. S/he will collaborate with FDA investigators at NCTR and with investigators in other FDA centers such as the Center for Drug Evaluation and Research (CDER). During the project, s/he will be actively encouraged to present the research at internal and external meetings and publish the findings in peer-reviewed journals.

Anticipated Appointment Start Date: September 1, 2021; start date is flexible

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 Jefferson, Arkansas, 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 doctoral degree in one of the relevant fields, or be currently pursuing the degree with completion by August 31, 2021. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Strong background in any modeling and simulation software (e.g., R, Berkeley Madonna, acslX, MCSim, Matlab, etc.)
- Knowledge of pharmacokinetics and toxicological principles
- Demonstrated written and oral communications skills

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 8/31/2021 11:59:00 PM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (46 👁)
  - **Mathematics and Statistics** (10 👁)