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Opportunity Title: FDA Modeling and Simulation Fellowships
Opportunity Reference Code: FDA-CDER-2024-1409

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

Reference Code FDA-CDER-2024-1409

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 9/30/2024 3:00:00 PM Eastern Time Zone

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

CDER Office/Lab and Location: Multiple research opportunities are currently available at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

The Division of Quantitative Methods and Modeling (DQMM) in the Office of Research and Standards (ORS) within the Office of Generic Drugs (OGD) provides expertise in advanced quantitative methods for the generic drug research program and conducts regulatory science and research activities based on quantitative approaches. Some of the responsibilities residing in DQMM include providing quantitative method support for guidance development, abbreviated new drug application (ANDA) reviews, citizen petitions, controlled correspondence, pre-ANDA meetings, methodology development for bioequivalence evaluation, active ingredient sameness demonstration, and post marketing safety surveillance. This Division coordinates modeling, simulation, data analysis and data mining, and establishes the scientific computing infrastructure for OGD. DQMM is also developing innovative quantitative approaches to improve regulatory decision making for generic drugs by fully utilizing the large amount of data available to FDA.

DQMM is a fast-paced, dynamic scientific environment with opportunities to collaborate with dedicated, energetic senior researchers who want to make a difference and improve public health. We are looking for several qualified individuals to participate in research activities that support our mission of providing high quality generic drugs to the American consumer.

Research Project: This opportunity in DQMM will provide an outstanding opportunity to learn and apply quantitative analysis, modeling, and simulation to support the aforementioned activities.

Learning Objectives: Under the guidance of a mentor, the research participant will be involved in the following areas:

- Modeling and simulation of modified release solid oral products to ensure consistency and quality of bioequivalence (BE)

recommendations (e.g., physiologically based pharmacokinetic (PBPK) absorption models, in vitro - in vivo correlations and pharmacokinetic/pharmacodynamic (PK/PD) modeling).
- Modeling and simulation to reduce/replace in vivo BE studies (i.e., in vivo PK BE studies, clinical endpoint or pharmacodynamic endpoint BE studies) for complex generic products and other generic products with clinical study challenges.
- Develop/apply PBPK absorption models for oral drug products to support biowaiver and risk-based BE assessment.
- Innovative approaches to establish active ingredient sameness/pharmaceutical equivalence for complex drug substances.
- Application of PBPK and/or computational fluid dynamics models to develop new BE methods for locally acting drug products administered via non-oral routes.
- PK/PD modeling of narrow therapeutic index drugs and complex drug products and clinical trial simulation to aid risk-based BE evaluation.
- Conventional and model-based meta-analysis on drugs within same class or different classes.
- Develop/apply novel analysis approaches to detect and assess safety signals of generic products.
- Develop systems pharmacology-based methodologies to study drug actions underlying both therapeutic effect and adverse reactions.
- Build data infrastructure and analysis tools to increase ANDA review efficiency and quality.
- Use and development of artificial intelligence (AI), machine learning (ML) and large language models (LLMs) to promote business intelligence in the Agency (e.g., interactive AI expert systems).
- Integration of AI/ML models with conventional/mainstream PK modeling to improve the modeling efficiency (e.g., automatic PK model selection, ML based survival analysis, etc).
- Applications and development of data analytics approaches to support complex generic drug product development and regulatory assessment, e.g., whole profile comparison, multivariate analysis, etc.
- Analysis of real-world data and generation of real-world evidence to support generic drug post market surveillance and pharmacoeconomic analysis.

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 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.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (1 👁)

Affirmation

I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)

AND

I have read the FDA Ethics Requirements.