

Opportunity Title: FDA Quantitative Systems Pharmacology (QSP) Research Fellowship

Opportunity Reference Code: FDA-CDER-2024-1453

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

Reference Code FDA-CDER-2024-1453

How to Apply *To submit your application, scroll to the bottom of this opportunity and click **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

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.

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Application Deadline 10/31/2024 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), Office of Clinical Pharmacology, Office of Translational Sciences., located at Silver Spring, Maryland.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

Research Project: This project is located in the Office of Clinical Pharmacology, Office of Translational Sciences. Paroxysmal nocturnal hemoglobinuria (PNH) is an extremely rare and life-threatening acquired disorder of hematopoietic stem cells. The clinical symptoms of PNH arise due to disrupted complement regulation affecting key blood elements such as red blood cells (RBCs) and platelets. Although current treatments have improved the management of PNH, there are still several challenges associated with these therapies. To provide confirmatory evidence to support regulatory approval decision on drug candidates, a Quantitative Systems Pharmacology (QSP) model for patients with PNH will be developed by integrating various sources of data. This QSP model will provide valuable insights into the underlying mechanisms of the disease,



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the effects of current treatments, and potential therapeutic interventions in PNH patients. Moreover, the QSP model will be tailored to pediatric patients.

Learning Objectives: Under the guidance of the mentor, the participant will learn how to build a QSP model and generate corresponding virtual populations. Briefly, the participant will learn to collect data and build a database. The participant will need to analyze model parameters with the collected data and perform model parameter sensitivity analysis, and further calibrate the model parameters. The participant will learn how to validate a QSP model with available data and generate virtual patients for further model application.

Anticipated Appointment Start Date: 2024. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is part time.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the [Guidelines for Non-U.S. Citizens Details page](#) of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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](#).

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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 bachelor's, master's, or doctoral degree in the one of the relevant fields. Degree must have been received within the past five years, or anticipated to be received by 6/30/2025.

Preference given to doctoral degree in Applied Mathematics, Statistics, System Biology, Computer Science or a related STEM field. Qualified masters and bachelor's in system biology may also be considered provided that the candidate demonstrates strong background in ordinary differential equations and proficient coding skills with MATLAB.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2025 12:00:00 AM.
- **Discipline(s):**
 - **Life Health and Medical Sciences** ([2](#))
 - **Mathematics and Statistics** ([11](#))

Affirmation I am a U.S. citizen, or 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.