Opportunity Title: FDA Quantitative Biomarkers Fellowship
Opportunity Reference Code: FDA-OWH-2022-01

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

Reference Code FDA-OWH-2022-01

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
- Cover letter (submit in the writing sample section)
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Three educational or professional recommendations

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 11/22/2021 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available with the Office of the Commissioner (OC) Office of Women's Health (OWH), U.S. Food and Drug Administration (FDA). The project will be located at the Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Laboratories (OSEL) located in Silver Spring, Maryland.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes public health by assuring the safety and effectiveness of drugs, vaccines and medical devices. The Office of Science and Engineering Laboratories (CDRH/OSEL) accelerates patient access to innovative, safe and effective devices through best-in-the-world regulatory science.

JOIN A TEAM LEADING INNOVATION IN IMAGE SCIENCE FOR REGULATORY EVALUATION

The Division of Imaging, Diagnostics, and Software Reliability (DIDSR) develops methods for evaluating emerging medical imaging systems. Our research programs directly impact FDA's regulatory assessments in areas including:

- Artificial Intelligence (AI)/ Machine Learning (ML)
- whole slide images (WSI) and digital pathology
- Extended-reality (AR/VR) devices
- Clinical trial design
- In silico trials
- Imaging physics

For more information, visit: https://www.fda.gov/about-fda/cdrh-offices/office-science-and-engineering-laboratories.

The selected participant will collaborate closely with a multidisciplinary

research group (engineers, physicists, and clinicians) to develop quantitative biomarkers for the evaluation of bone health using radiomics and machine learning. The project aims to design and validate a realistic computational model of trabecular bone. The phantom will be used to develop CT-based texture biomarkers for assessing fracture risk in osteoporosis and for monitoring the response to osteoporosis drugs. Additionally, the phantom will be 3D-printed to aid in the evaluation of novel high-resolution CT scanners.

Under the guidance of a mentor, the participant will be involved in the following activities:

- Phantom/biomarker development efforts will include:
  - Modeling and simulations
  - Image analysis using radiomics and machine learning
  - 3D printing
  - Mechanical testing
- Learn about regulatory science development at the FDA
- Contribute to the Agency's regulatory efforts by providing technical expertise
- Disseminate findings and regulatory science tools in conferences and peer-reviewed paper publications

Anticipated Appointment Start Date: 2021

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 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:

- Strong background in the fundamentals and an eagerness to solve technical challenges systematically with experimental and/or computational approaches
- Fluent in Python or MATLAB
- Experience in image processing, analysis, and/or 3D printing

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (3 👁)
  - **Mathematics and Statistics** (10 👁)
  - **Physics** (16 👁)

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