

Opportunity Title: FDA Post-master Science and Engineering Fellowship

Opportunity Reference Code: FDA-CDRH-2022-14

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

Reference Code FDA-CDRH-2022-14

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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
- Cover Letter (upload to Writing area)
- 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 <a href="MRISE.FDA.CDRH@orau.org">ORISE.FDA.CDRH@orau.org</a>. Please include the reference code for this opportunity in your email.

Application Deadline 6/27/2022 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Division of Applied Mechanics (DAM) within the Office of Science and Engineering Labs (OSEL) at the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

Histotripsy is a pulsed high intensity ultrasound therapy for non-invasive tissue destruction. During histotripsy procedure bubble clouds will be generated from endogenous gas in tissues. Very high ultrasound pressure causes bubbles to burst and impart intense localized strain that can generate targeted, therapeutic lesions. Histotripsy can be used for tumor ablation for a broad range of cancer applications, including tumors in the pancreas, kidney, breast, prostate, uterus, thyroid, and brain. In addition, it has been investigated for treatment of neuroglial, heart, and valvular diseases. However, there is the possibility of thermal damage to the surrounding tissue in the patients. This project aims to develop and validate a tool to assess thermal safety of these devices that will help manufacturers to improve clinical trial design, while reducing the need for in-vivo animal studies.

During this research project, the selected fellow will receive broad biomedical research training in various aspects of physics, engineering and biological testing. Under the guidance of a mentor, the fellow will be involved with the following research activities:

• 1) Perform benchtop experiments using an ultrasound transducer system and tissue mimicking phantom to investigate the effects of key test parameters (frequency, acoustic powers, pulse duration, etc.) on



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the temperature distribution inside the phantom

- 2) Conduct computational modeling of ultrasound-induced pressure and temperature fields in the phantom during histotripsy procedures
- 3) Analyze computational and experimental results, perform statistical analyses, and conduct required steps in model validation

## Anticipated Appointment Start Date: August 1, 2022; 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 on-site for laboratory research 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 (OPM) 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 master's degree in one of the relevant fields, or be currently pursuing the degree with completion by August 1, 2022. Degree must have been received within the past five years.

## Preferred skills:

- Strong background in physics and mathematics (Previous research experience in acoustics or heat transfer especially valuable)
- Hands-on experience in a physics or engineering laboratory
- · Experience with data acquisition, instrument control, and signal processing
- · Experience with programing (particularly Matlab) and statistical analysis
- · Excellent scientific writing and communication skills

## Eligibility Requirements

• Citizenship: LPR or U.S. Citizen

• Degree: Master's Degree received within the last 60 months or anticipated to be received by 8/1/2022 11:59:00 PM.

• Overall GPA: 3.50

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- Academic Level(s): Graduate Students or Post-Master's.
- Discipline(s):
  - o Engineering (<u>3</u> ●)
  - Mathematics and Statistics (1\_●)
  - Physics (<u>2</u>●)

**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.)

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