Opportunity Title: FDA Development of a Queryable Technological Parameter Library for Energy-Based Surgical Devices Indexed by Indications for Use (IFU)
Opportunity Reference Code: FDA-CDRH-2026-0034

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

Reference Code FDA-CDRH-2026-0034

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

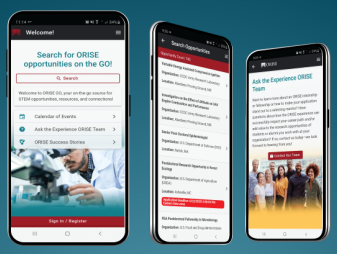
All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDRH@orau.org. Please include the reference code for this opportunity in your email.

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Application Deadline 1/29/2027 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 Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA).

Oak Ridge Institute for Science and Education (ORISE) Research Participation Programs at the U.S. Food and Drug Administration are educational training programs designed to provide students and recent graduates, opportunities to participate in project-specific research and developmental at the Center for Devices and Radiological Health (CDRH). The mission of CDRH is to protect and promote public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, caregivers, and providers with understandable and accessible science-based information about products. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Research Project: This project involves the systematic identification, extraction, and organization of key treatment parameters (e.g., power output, exposure time, frequency) and technical parameters (e.g., wavelength, impedance, beam profile) across a range of EBSDs, mapped directly to their corresponding clinical indications. You will conduct a comprehensive review of FDA marketing authorizations, applicable consensus standards, and relevant clinical literature to populate a centralized, queryable library or workspace with the platforms of ELSA,

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Python Vibe Coding, and CDRH-CARS System. This resource will enable reviewers to rapidly surface relevant parameter benchmarks, compare device specifications against cleared predicates, and identify gaps in submitted data. Furthermore, the outcomes of this project may further the development of FDA guidance documents, providing stakeholders with a valuable resource to inform and prepare their premarket submissions. For example, stakeholders could utilize consolidated performance tests with a better understanding of performance criteria and parameters for specific device types (example: FDA guidance on performance criteria for MR systems; https://www.fda.gov/media/133250/download)

Learning Objectives: Under the guidance of a mentor, you will:

- Understand how to systematically identify and extract treatment and technical parameters from energy-based surgical devices (EBSDs), including metrics such as power output, exposure time, wavelength, impedance, frequency, and beam profile.
- Develop the ability to map device parameters to their corresponding clinical indications to support comparative device evaluation and regulatory review.
- Gain experience conducting comprehensive reviews of FDA marketing authorizations, consensus standards, and relevant clinical literature.
- Learn how to organize and curate regulatory and technical data into a centralized, queryable library or workspace.
- Build familiarity with the use of AI-enabled and regulatory informatics platforms, including ELSA, Python Vibe Coding, and the CDRH-CARS System.
- Strengthen skills in benchmarking device specifications against cleared predicate devices to support premarket review activities.
- Identify and evaluate gaps in submitted performance and safety data for EBSD premarket submissions.
- Understand how consolidated technical and clinical evidence can support the development of FDA guidance documents and reviewer resources.
- Recognize how standardized parameter libraries and performance benchmarks can improve consistency, efficiency, and transparency in regulatory decision-making.
- Explore how stakeholders can use consolidated performance testing information and parameter criteria to better prepare premarket submissions for specific device types.

Mentor: The mentor for this opportunity is Linli Shi (Linli.Shi@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: Fall/Winter 2026. 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 full time.

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Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

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.

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.

Point of Contact Richard

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17)
  - **Engineering** (29)
  - **Life Health and Medical Sciences** (1)
  - **Physics** (16)

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.)