Opportunity Title: FDA CDRH Postdoctoral Fellowship
Opportunity Reference Code: FDA-CDRH-2023-05

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

Reference Code FDA-CDRH-2023-05

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. Your application will be considered incomplete and will not be reviewed until one recommendation is submitted.

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.

Application Deadline 5/13/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Office of Science and Engineering Laboratories (OSEL), within the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) located in Silver Spring, Maryland.
The first aim of the project is to evaluate performance of continuum-based finite element models for quantifying bone-screw pullout strength. The second aim is to rigorously calibrate a high-resolution screw-pullout FE model using microscale bone-screw interface mechanics.

The activities involved in this appointment are listed below:
Aim 1: Evaluate performance of continuum-based finite element models for quantifying bone-screw pullout strength.
Aim 1.1: Design mock metallic bone screw with generic features.
Aim 1.2: Use current microCT scanner to generate 3D continuum FE model of bone-screw pullout test.
Aim 1.3: Design and build fixtures to perform ASTM F543 pullout testing.
Aim 1.4: Publish manuscript comparing and contrasting continuum FE model pullout strength predictions to bench test results.
Aim 1.5: Release a points-to-consider document to review submissions utilizing continuum bone-screw stress predictions to establish substantial equivalence.
Aim 2: Rigorously calibrate a high-resolution screw-pullout FE model using microscale bone-screw interface mechanics.
Aim 2.1: Procure and purchase an in situ loading device for in-house Scanco uCT 100 instrument.
Aim 2.2: Design and manufacture a non-metallic holding device for performing F543 testing in a uCT scanning tube with simultaneous loading

of the bone screw.
Aim 2.3: Develop a Mimics pipeline to generate FE models from uCT image stacks from Aim 1.2.
Aim 2.4: Calibrate FE model and publish manuscript describing development and calibration of a bone screw pullout FE model.

Through this appointment, the potential candidate will learn how a computational model is calibrated, verified, and validated according to the exacting standards established by the FDA and ASME V&V 40 guidelines. The candidate will learn how to use a novel testing device interfaced with a state-of-the-art microCT scanner. The candidate will develop and enhance their programming skills by writing custom code to build and run high-resolution models of bone-screw pullout testing. The candidate will get exposure to ASTM testing standards such as ASTM F543 and learn how to use hydraulic testing machines. The candidate will have substantial opportunities to be exposed to how FDA regulates medical devices and how to develop projects in the realm of regulatory science.

Anticipated Appointment Start Date: April 2023; start date is flexible

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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 a doctoral degree in either Mechanical or Biomedical Engineering with a focus on Orthopaedic Implants and/or Computational Modeling. Degree must have been received within the past five years.

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Preferred candidates should have demonstrated academic or professional experience with some of the following:

- Experience with Finite Element Analysis packages such as Abaqus, Ansys, FEBio
- Significant experience using programming languages such as Matlab, Python, C++, or R
- Experience with image analysis programs such as Mimics, Amira, 3D Slicer, or VGStudio MAX
- Experience with CAD tools such as Solidworks, PTC Creo, or Fusion 360
- Candidate should have experience publishing at least 2 peer-reviewed manuscripts in PubMed listed journals
- Experience with collecting and analyzing high-resolution image stacks from microCT scanners

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Engineering** (27 👁)
- **Age:** Must be 18 years of age

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.)