CERSI:
Center for Excellence in Regulatory Science and Innovation (CERSI) is a collaboration between UCSF, Stanford, and the FDA focusing on research and the scientific exchange between academia and the FDA.

Background:
In 2016, CERSI funded a collaboration between Dr. Jeffrey Lotz (UC San Francisco) and engineers at the FDA Office of Science and Engineering Laboratories to conduct an initial systematic review of finite element analysis (FEA) in FDA spinal fusion cage 510(k) submissions over the previous five years. This review revealed the majority of FDA submissions containing FEA lacked critical information and were not useful to government regulators. A subsequent industry survey revealed that industry stakeholders desired a roadmap containing fully prescribed FEA best practices. Together, these efforts emphasized the need for FDA to clearly communicate spinal cage modeling expectations to industry stakeholders. Thus, the project goal is to define best practices for computational evaluation of spinal fusion cages.

Under the mentorship of scientists and engineers working in the Office of Science and Engineering Laboratories at FDA, the incumbent will deliver the following by the end of the summer:
- A validated finite element model framework simulating mechanical performance testing of spinal fusion cages.
- Contribute to the computational modeling of spinal fusion cages best practices document
- Outline and initiate a parametric finite element analysis study to determine the most influential factors in assessing the mechanical performance of spinal fusion cages in a computational framework
- Present any non-confidential findings at the Center for Disruptive Musculoskeletal Innovations (CDMI) Fall Symposium at UC San Francisco in September/October 2019

Position Information:
- Full-time, summer position at the FDA in Silver Spring, MD
- Starting in June 2019 for about 3 months (beginning and end dates are flexible)
- Access to FDA seminars/workshops on future direction of new biotechnology (i.e., scientific computing/big data, small business regulation, etc, for more see: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm, http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm)
- Access to industry stakeholders via the CDMI

Qualifications:
- Graduate Student or Medical Student with at least a B.S. in Mechanical or Bioengineering preferably with classes in mechanical engineering. We may consider senior undergraduates who have fundamental knowledge of FEA.
- Knowledge and experience with Finite Element Modeling
- Excellent verbal and written communication skills
- Interest in computational modeling, medical device development, and regulatory issues

If you are interested, please email Dr. Dezba Coughlin (dezba.coughlin@ucsf.edu) your resume with the Subject, FDA INTERNSHIP, by May 6, 2019. In the email, state why you are interested in the position and why you are the best candidate for this opportunity.