JOHNS HOPKINS
Center for Environmental & Applied Fluid Mechanics

FALL 2020 CEAFM VIRTUAL SEMINAR

"Initiating a Medical Device Clinical Trial Using Modeling and Simulation"

Presented by Dr. Brent Craven

U.S. Food and Drug Administration

Hosted by Rajat Mittal (JHU - MechE)

Computer modeling is frequently used as a complement to bench-top experiments in medical device submissions to the U.S. Food and Drug Administration (FDA), but is rarely used as a primary source of evidence. Modeling and simulation (M&S) are expected to play a growing role in future medical device submissions with continued advances in computational capabilities and wider adoption by industry. This has the potential to significantly reduce time to market and expedite patient access to life-saving technology if the credibility of M&S results can be ensured and the FDA can streamline the review of M&S data. FDA guidance for reporting M&S data in regulatory submissions is available and the ASME V&V 40 standard for assessing the credibility of M&S of medical devices through verification and validation (V&V) has been published. However, these documents together have yet to be implemented or assessed in a publicly available realistic case study. In this talk, I will provide an overview of a collaborative research project aimed at providing an end-to-end example of using M&S as a primary source of evidence in a medical device regulatory submission to the FDA. The objectives of this ongoing project are to: • design and fabricate a generic medical device (an inferior vena cava blood clot filter); • perform simulations and acquire experimental data to demonstrate M&S credibility for two of the most burdensome pre-clinical bench tests required for assessing device performance (fatigue resistance and clot trapping efficiency); • prepare a mock regulatory submission to initiate a clinical trial using M&S as a primary source of evidence; • have an independent FDA review team evaluate the mock submission; and • assess and improve the regulatory review process and M&S guidance and standards. All of the results of this project will be made publicly available. This study will, thus, serve as an example for industry in the use of M&S in medical device regulatory submissions to the FDA.

Friday, November 13, 2020 at 3:00 PM

https://wse.zoom.us/j/93762992307