

## **Healthcare Engineering Lecture Series**

**Title:** FDA Premarket review of medical devices

**Speaker:** Brent L. Showalter, PhD, Assistant Director, Spinal Devices Division, Center for Devices and Radiological Health, US Food and Drug Administration (FDA), Silver Spring, MD

### **Education:**

- Ph.D., Bioengineering, University of Pennsylvania, Philadelphia, PA
- BS, Mechanical Engineering, Brigham Young University, Provo, UT

### **Qualifications:**

- MR Focal Point for Office of Orthopedic Devices, Center for Devices and Radiological Health, FDA
- Senior Lead Reviewer, Anterior Spine Devices Branch, Center for Devices and Radiological Health, FDA

**Time:** March 2, 2021, 4:00 – 5:20 pm

**Zoom:** <https://zoom.us/j/98890792479?pwd=eTZCV0JtSmxRTHRTN1A0UWhXNIB1dz09>

### **Abstract:**

The Center for Devices and Radiological Health (CDRH) within the U.S. Food and Drug Administration (FDA) works to ensure that patients have timely access to safe, effective, and high-quality medical devices. CDRH accomplishes this by advancing regulatory science and working to provide the medical device industry with predictable, consistent, and efficient regulatory pathways. This talk presents some general overview on medical device regulation and provides examples of spinal device regulation.

### **Biography:**

Dr. Brent Showalter is currently the Assistant Director for the Division of Spinal Devices at the FDA. This division regulates devices such as intervertebral body fusion devices, vertebral body replacements, total disc replacements, cervical plates, lumbar plates, annular repair devices, and nucleus replacement devices. He was the MR Focal Point for Office of Orthopedic Devices, in charge of review of MR Safety testing for all orthopedic implants, including total hip replacements, total knee replacements, total shoulder replacements, fracture fixation plates, pedicle screw systems, and intervertebral body fusion devices. He has also served as the Senior Lead Reviewer in the Anterior Spine Devices Branch for devices used in spine surgery, including intervertebral body fusion devices, total disc replacements, vertebral body replacements, pedicle screw systems, interspinous spacers, cervical plates, lumbar plates, and buttress plates. Prior to joining the FDA, Dr. Showalter studied intervertebral disc mechanics at the University of Pennsylvania and received a bachelor's in mechanical engineering from BYU.

### **Host/Organizer:**

Ming Chyu, PhD, PE

Professor, Department of Mechanical Engineering

Adjunct Professor, School of Medicine

Founder, College of Engineering Graduate Healthcare Engineering Option

Texas Tech University

Founding Editor-in-Chief, *Journal of Healthcare Engineering*  
Founding President, [Healthcare Engineering Alliance Society \(HEALS\)](#)