The Food and Drug Administration's (FDA's)
2015 ORSI Science Symposium
April 27, 2015
SPEAKER ABSTRACTS AND BIOGRAPHIES

Session 1: Centers for Excellence in Regulatory Science and Innovation (CERSIs) Presentations – 8:35-11:30 AM

University of Maryland CERSI

CERSI	**University of Maryland**
Speaker	**William E. Bentley, PhD**
Title and Location	**Robert E. Fischell Distinguished Professor & Chair** **Fischell Department of Bioengineering** **University of Maryland, College Park, MD**
Biography	**William E. Bentley is the Robert E. Fischell Distinguished Professor of Bioengineering and founding Chair of the Fischell Department of Bioengineering at the University of Maryland. His B.S. and M.Eng. degrees were from Cornell University; his Ph.D. from the University of Colorado. All were in chemical engineering. At Maryland since 1989, Dr. Bentley research has focused on the expression of biologically active proteins, deciphering and manipulating cell-cell communication pathways, and connecting microfabricated devices with biological systems via "biofabricated" interfaces. He has authored over 250 archival publications and mentored 33 PhDs and 22 postdocs. He is co-PI of Maryland's Center of Excellence in Regulatory Science and Innovation (CERSI), a joint initiative with the FDA. He is co-PI of the National Capital Consortium for Pediatric Device Innovation (www.innovate4kids.org), funded by the FDA's Office of Orphan Products Development. Dr. Bentley was recipient of the Charles Thom Award of the SIMB, the AIChE's FPB Division Award, and the ACS BIOT Division's Marvin Johnson Award. He is also a Fellow of the ACS, AAAS, and AIMBE and is an elected member of the American Academy of Microbiology.**
Presentation Title	**Science that speeds health innovation**
Presentation Abstract	**The UM-CERSI advances regulatory science by providing: 1) direct scientific and training linkages between the FDA and the two leading UM campus; and 2) cutting edge regulatory science research experiences for teams of FDA and UM personnel in collaborative research projects. These projects have been diverse, reflecting the breadth of expertise at UMB and UMCP. They range from studies of "Antipsychotic drug use in nursing home (NH) elders with dementia", to "Development of Standards for the Evaluation of Conventional and Advanced Tissue Engineering Scaffolds," and "Best practices for transporter in vitro assays", to name a few. To-date, several validated standard methods have been developed and 18 research papers have been published in top tier scientific journals.** **The UM-CERSI Center-wide activities that promote regulatory science within the broader scientific community have also been tremendously successful. For example, to-date 1,895 FDA scientists and engineers have attended UM-CERSI seminars held monthly at the White Oak campus; 3,110 individuals from across the spectrum (FDA, academia, and industry) have attended the CERSI-sponsored workshops. Topics have also varied significantly, a few being: "Top Down Analysis of Antibodies", "Patient Focused Drug Development", and "AIMBE/NIH Workshop on Validation and Qualification of New In Vitro Tools and Models for the Pre-Clinical Drug Discovery Process". Finally, the UM-CERSI has started an MS program (> 50 students enrolled) within Pharmacy at UMB and an MEng Certificate (>20 enrolled) within Bioengineering at UMCP aimed primarily at practitioners seeking additional education and training in their career development.**