

**“International Workshop on  
Tissue Phantoms and Standardization in Biophotonics”  
Dr. Yu Chen-May 21, 2014**

Sponsored by CERSI Scientific Exchange Award, we successfully organized a one-day workshop titled “International Workshop on Tissue Phantoms and Standardization in Biophotonics” at the University of Maryland Campus. The primary objective of the workshop is to facilitate development of phantom-based test methods, build a foundation upon which rigorous, least burdensome consensus standards can be achieved and ensure FDA’s readiness to evaluate innovative and emerging optical imaging technologies.

**19 invited lectures** were given by experts in the field of optical imaging and phantom development, from worldwide (including USA, Canada, Germany, Japan, and Netherlands). The lectures covered topics including both role of phantom-based methods in regulatory process, and phantom development and standardization for various important biophotonic imaging technologies including Optical Coherence Tomography (OCT), Near Infrared Spectroscopy (NIRS), Diffused Optical Tomography (DOT), Hyperspectral Imaging and Fluorescence Imaging. Experts in the regulatory agencies such as FDA concluded the importance of phantom-based test methods, and addressed the extent and type of effort required for phantom development. Frontiers in the field of tissue phantom development and clinical application of biophotonic imaging shared the current advance in the development and application of tissue phantoms, in terms of materials and methods (including performance characteristics, figures of merit, data processing steps) for phantoms instrumental for quantitative analysis, evaluation and validation of optical imaging devices, as a foundation for standards documents to address key optical imaging devices technologies.

**55 attendees** from governmental institutions (52%), academia (42%) and industry (6%) attended the meeting and joined the discussion. Among all the attendees, 21 (38%) were from FDA, including both scientists and reviewers. Through the lectures and discussions, it was concluded that there is a general lack of knowledge in the biophotonics field regarding international consensus standards. Improvement in the communication in the field of phantom-methods development and regulatory agencies, and greater understanding and appreciation in the quality of standards-relevant research being performed will likely lead to speeding up the process from phantom development to prevalent application, which will eventually lead to standardization of the methods and be incorporated in the regulatory process.

The workshop marked the formation of a community of scientists and regulators in the field of regulatory science for biophotonics imaging. The discussion will continue, and we expect more collaboration and rapid advance in the field will happen along the way, which leads to rigorous consensus standards that will enhance FDA’s ability to evaluate innovative and emerging optical imaging technologies.