# 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**

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| CERSI | **University of Maryland** |
| Speaker | **Bruce Yu, PhD** |
| Title and Location | **Associate Professor of Pharmaceutical Sciences**<br>**University of Maryland, Baltimore, MD** |
| Biography | **Dr. Yu received his B.S. in biochemistry from Peking University and Ph.D. in biophysics from the Johns Hopkins University. His postdoctoral training was in NMR spectroscopy at SUNY Buffalo and peptide chemistry at the University of Alberta. In his independent research career at the at the University of Utah and at the University of Maryland, Dr. Yu has worked on developing magnetic resonance imaging agents and biomaterials . His current research interest is to develop noninvasive chemical analysis using NMR for product inspection, especially for pharmaceutical solutions. Dr. Yu received the Kimmel Scholar Award in 2004 and the Presidential Early Career Awards for Scientists for Engineers in 2005.** |
| Presentation Title | **Noninvasive Detection of Protein Aggregation using Water Proton NMR** |
| Presentation Abstract | **Protein drugs have a tendency for from harmful aggregates in solutions. Such aggregation can occur in finished drug products due to various physical stresses, such as agitation and heating, commonly encountered transportation and storage. Currently, once a protein drug vial if filled and sealed, only visual inspection is possible. This is because existing aggregation detection techniques are invasive; they require opening the drug vial and drawing out a portion of the drug solution for analysis.**<br><br>**Giving aggregated protein drugs to patients is avoidable if the aggregation level in each vial is assessed right before injection. This requires a simple noninvasive aggregation detection technique.**<br><br>**In this presentation, we report such a technique based on the water proton NMR signal. Aggregation detection is conducted non-invasively by putting an unopened vial of protein solution into a low-field benchtop NMR spectrometer. Because water is the solvent of every biopharmaceutical solution, this technique has wide applicability. The measurement process is simple and fast.** |