

## Biologics Workshop Final Report

University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)  
Science Exchange and Conference Grants  
and Bio- and Nano-technology Center (BNTC) at the University of Maryland

The program, “Protein aggregation measurement in biotherapeutics: established and emerging techniques”, was held on December 5, 2016 at the University of Maryland School of Pharmacy from 8:30am to 5:30pm. It was a joint event between MCERSI and BNTC. The workshop focused on analytical techniques for detecting and quantifying protein aggregates in biologics. The workshop provided an opportunity for experts from industry, academia, and regulatory agencies to share the latest development on analytical technologies for detecting protein aggregation in biologics.

The workshop started with Dr. Bruce Yu of the University of Maryland presenting examples where current quality control system failed to detect some serious defects in biologic products. Dr. Ewa then presented the background for this workshop, and made the case for technology development in this area. Their opening remarks were followed by four sessions; two in the morning and two in the afternoon. Each session has three presentations, each of 20 minutes, and one panel discussion, of 30 minutes. The first session overviews the regulatory and technical challenges for aggregation analysis in biologics with the speakers from FDA and industry. The second session focused on various established technologies currently employed by the industry; all three speakers in this session are from industry. The third and fourth sessions are devoted to emerging technique with a mixture of industry, government and academic speakers. The emerging techniques discussed include optical techniques for particle counting and shape characterization (third session), and NMR and mass spectrometry techniques (fourth session).

The program was a success with 94 in-person participants, include 26 from FDA, 28 from industry and 40 from academia.

The workshop was co-organized by Dr. Bruce Yu from the University of Maryland Baltimore and Dr. Ewa Marszal from the FDA. Session chairs include: Dr. Rugman De Silva from the FDA; Dr. Brian Lobo from MedImmune; Dr. Dean Ripple from NIST and Dr. Thomas Spitznagel from Macrogenics. Dr. Nataline Eddington, Dean of the University of Maryland School of Pharmacy, gave welcome remarks at the beginning.