**Seminar:** University of Michigan, Department of Pharmaceutical Sciences

**Date:** April 20, 2016

**Speaker:** Professor David Volkin, Department of Pharmaceutical Chemistry, University of Kansas

**Title:** Probing the Interface of Protein Stability Analysis, Formulation Development and Biosimilarity Assessments

**Abstract**: This presentation will cover some of the challenges and opportunities of performing “fingerprint analysis” of various protein analysis data sets (e.g., primary and higher-order structure, potency, physicochemical stability, etc.) and applying the results to both formulation development and biosimilarity assessments. Topics will include (1) different mathematical approaches to evaluate combined data sets from analysis of protein stability, and (2) applying these tools to a case study comparison of various well-defined IgG1-Fc glycoforms. These results were recently published in a series of four back-to-back papers in the February 2016 issue of *Journal of Pharmaceutical Sciences*.