The statistician’s roles as teacher, student, and scientific partner are described within the CMC pharmaceutical community. Contrasts between academe and industry are provided to demonstrate differences and similarities in these environments. Examples in process characterization and biosimilar analytical comparability are used to show the changing role of the statistician, and the need to assume each role at some time during a scientific investigation. Lessons learned from this process will be shared with the audience.

BIO: Richard (Rick) K. Burdick is an Emeritus Professor of Statistics, Arizona State University (ASU) and former Quality Engineering Director for Amgen, Inc. for 10 years. He presently serves as Principal for Burdick Statistical Consulting, LLC located in Colorado.

Rick Burdick received his PhD in Statistics from the Department of Statistics at Texas A&M University under the supervision of Larry J. Ringer. He is a recipient of the H.O. Hartley Award. His research and consulting interests consider statistical applications in the CMC pharmaceutical industry including comparability studies, stability data analysis, analytical method validation, quality by design process characterization, and analytical similarity for biosimilar products. He has written over 80 journal articles and four books.

Burdick is a Fellow of the American Statistical Association (ASA) and a member of the American Society for Quality (ASQ) and the American Association of Pharmaceutical Scientists (AAPS). He served on the USP Statistics Expert Committee from 2010-2020.