



International Alliance for  
Biological Standardization

## 12th Annual Statistics Workshop: From Data to Patients – CMC Statisticians' Contributions to Quality, Safety, and Efficacy of Pharmaceutical Products

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**The fundamental role of frequentist statistics in CMC decision making** – Rick Burdick,  
Burdick Statistical Consulting, LLC

The Food and Drug Administration (FDA) draft guidance “Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products,” issued in July 2023, listed the term “statistics” or “statistical” over 30 times and recommended to “consult with a statistician before discussing the study design and statistical approach with FDA.” The European Medicines Agency (EMA) document “Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development” issued in 2021 cited these same words over 80 times. It is clear that statistical analysis is critical for the successful development and manufacturing of pharmaceutical products. Peterson et al. (2009) provides an excellent description of the statistical techniques to support these activities. This talk will provide a statistical toolbox including interval estimators, regression modeling, hypothesis testing, process control, and mixed models. To some this may seem like a modest toolbox, but it will be demonstrated that these tools can be used in a variety of critical CMC applications.

