



International Alliance for
Biological Standardization

10th Annual Statistics Workshop: Science & Statistics – Elevating CMC through Partnership

November 12-14, 2024
IBBR, Rockville, USA

Session IV: Enhancing Analytical Method Transfer and Assessing Manufacturing Analytical Comparability: Statistical Approaches and Empowering Subject Matter Experts

This conference session will feature presentations addressing the statistical aspects of analytical method transfer and manufacturing analytical comparability. One presentation focuses on empowering subject matter experts (SMEs) in method transfer by providing them with the necessary statistical training. Another presentation discusses statistical approaches for assessing manufacturing analytical comparability, considering the challenges posed by highly variable data and limited batch sizes in cell and gene therapies. These presentations aim to highlight the importance of statistical consultation and the impact on overall quality and efficiency in the pharmaceutical industry.

