



International Alliance for
Biological Standardization

11th Annual Statistics Workshop: Big Tent Statistics - Conveying the Importance of Statistical Contributions

October 20-23, 2025
Virtual Meeting

Title: Collaborating with Impact: Differentiating CMC Statistics in a Data-Driven Industry

CMC statisticians have often been viewed as service providers, engaged on an as-needed basis for specific tasks. Today, the rise of data-intensive roles and advanced technologies creates an opportunity to redefine this perception. By integrating statistical rigor with process understanding, regulatory insight, and lifecycle thinking, CMC statisticians can become strategic partners who drive drug development and enhance product quality.

This talk will explore how statisticians can differentiate themselves and deliver measurable business value through collaboration. Key contributions include:

1. **Designed experimentation** to build robust, efficient methods and processes,
2. **Bayesian, risk-based decision-making** aligned with regulatory expectations, and
3. **Multivariate approaches** that enable real-time release testing (RTRT) in continuous manufacturing and improved quality outcomes

Real-world examples—such as PPQ acceleration, surrogate modeling, and strategies to enhance patient centricity—will illustrate how these capabilities set CMC statisticians apart from other quantitative stakeholders. By leveraging these differentiators, statisticians can move beyond a support role to become equal partners in shaping the future of drug development.

