



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: CMC Statistics in a Data Science World**

Digital transformation is the rage in the pharmaceutical industry. Companies are looking to develop and grow data science teams with a desire to utilize Gen-AI and machine learning to cut costs and improve decision making. Statisticians, CMC statisticians in particular, are the original data scientists marrying domain knowledge with advanced data analysis capabilities who are finding themselves in competition and often left behind in the data science movement. While these roles often employ similar methods—statistical modeling, machine learning, and large-scale data analysis—the unique contributions of CMC statisticians remain essential for ensuring drug quality, regulatory compliance, and manufacturing excellence. Drawing on my experience leading both CMC statistics and data science teams, I will explore the differences and synergies between these disciplines. I will highlight how CMC statisticians' deep understanding of the product lifecycle, regulatory expectations, and process robustness distinguishes their contributions, while also demonstrating how data science can enhance and complement traditional statistical approaches. Finally, I will discuss strategies for statisticians to effectively advocate for their impact, articulate their value to leadership, and position themselves as indispensable partners in an increasingly data-driven landscape.

