



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: Recognition & Collaboration: A Customer's Perspective**

Statisticians can be transformative partners when engaged at the moment problems are defined—not after designs are locked. From the customer's perspective, this session shows how early statistical involvement elevates decision quality, compresses timelines, and strengthens regulatory credibility. Using real-world vignettes (comparability, investigations, and inspection-ready quality analytics), we outline a practical engagement model: a decision-making governance co-authored with statistics, governance gates requiring statistical sign-off, and reviews before pivotal milestones. We also highlight small-n toolkits (tolerance intervals, t-tests, and other process monitoring tools) that translate uncertainty into clear decision-making criteria. A leadership lens details structural, incentive, and cultural levers that normalize early engagement—RACI ownership for decision quality, and a “one slide of math” ritual for GMP and other major decisions. Attendees should take away a plan to reposition statisticians as strategic co-architects of outcomes—early, often, and credibly.

