



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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Beyond the Spreadsheet: Strengthening CMC Data Governance as the Foundation for Advanced Analytics and Regulatory Compliance – Sara Cook, Iliacook Statistical Consulting, LLC.

As Chemistry, Manufacturing, and Controls (CMC) datasets grow in complexity, the traditional silos between data collection and statistical analysis are becoming untenable. This presentation explores the strategic role of data governance not merely as an administrative task, but as the essential architecture required to support the modern CMC lifecycle.

Effective data governance directly impacts the reliability of Statistical Software; without robust data integrity and standardized formats, even the most advanced validated platforms risk "garbage in, garbage out" scenarios. Furthermore, this foundation is a prerequisite for the adoption of sophisticated Methodologies. While Bayesian methods, AI, and machine learning offer transformative potential for process optimization, their predictive power is strictly limited by the quality and traceability of the underlying data.

From a Regulatory Review perspective, health authorities increasingly expect a holistic "data-first" approach. By implementing strategic data systems early in the development cycle, sponsors can ensure seamless data packages that withstand rigorous global audits. This session will outline best practices for statisticians to lead data quality initiatives, ensuring that CMC data is not just stored, but is strategically managed to enable high-velocity innovation and regulatory submissions.

