



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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From Data to Insight: Enabling Scalable, GxP-Compliant Analytics Through an Integrated Data Lake - Brenda Ramirez – Kite Pharma, a Gilead Company

As data volume and complexity grow in pharmaceutical manufacturing, statisticians are increasingly challenged to translate fragmented data into reliable, actionable insights. Traditional approaches—often dependent on manual processes and disconnected systems—limit visibility, slow decision-making, and introduce inefficiencies.

Beyond analysis, statisticians play a critical role in defining how data are structured, standardized, and governed to ensure they are fit for purpose in a regulated environment. Their perspective shapes key elements such as analytical data models, parameter harmonization, and data quality frameworks—ensuring the data lake supports meaningful, interpretable, and defensible analyses.

The talk will highlight how statisticians, in collaboration with IT and quality, drive the development of scalable, compliant data systems that support decision-making. This perspective underscores the evolving role of the statistician—from data consumer to architect of data ecosystems that ultimately enhance product quality and patient outcomes.