



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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The growing influence of Bayesian methods in uncertainty quantification, inference, and modeling in CMC studies – Stan Altan, Fellow, JJIM Statistics and Decision Sciences

Bayesian methods provide a coherent, probability-based framework for estimation, inference, and prediction. They are particularly valuable to CMC statisticians, who are engaged in the design of experiments, complex hierarchical (linear and nonlinear) models, and cross-sectional data collection. Bayesian methods help address the central goal of CMC studies: elucidating relationships between quality attributes and process/formulation parameters, thus ensuring safety and efficacy. Bayesian methods can be regarded as facilitating patient centric quality consideration.

This presentation reviews the published literature on Bayesian applications in the CMC space and traces the trajectory of their increasing adoption. I will highlight the range of CMC topics where Bayesian approaches have been applied and discuss practical considerations, including prior specification, predictive distributions, interpretability, and regulatory implications. Underpinning this trend is the fundamental appeal of probability based decision making offered by Bayesian methods.

