



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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Application of Bayesian Methodologies in CMC Statistics – Areas of Focus

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A demonstration of the use of Bayesian methodology in the of the CMC module of regulatory submissions with a focus on comparability and stability. The use of Bayesian methodology in the field of CMC statistics has been rapidly increasing with industry leading the way in the application of these methods leading to recent publications including “Case Studies in Bayesian Methods for Biopharmaceutical CMC”; Faya & Pourmohamad (2023). This presentation is taken from a regulatory perspective to illustrate how consideration of these methodologies is conducted and what particular methodological details i.e., model specifications are important to ensure a robust and informative assessment. The aim is to try and engage industry CMC statisticians for increased alignment between the industry and regulators on this topic. Additionally, to highlight the advantages of how they can be used to strengthen submissions in light of lack-of-data issues and beyond.

