



International Alliance for
Biological Standardization

9th Annual IABS Statistics Workshop Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

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Title: Considerations in Prior Knowledge Development for Product Stability

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Bayesian statistics offers an inference approach that requires prior distributions for model parameters. These distributions must be selected for any given analysis and can vary from highly informative – confining the parameter within a narrow range – to weakly informative or relatively non-informative. This talk will explore how prior selection, and the use of targeted informative priors, can facilitate efficient conclusions. An example that determines product shelf-life using a Bayesian approach will be shared that offers a stronger product-wide inference statement than the ICH Q1E alternative. There will be additional discussion on the prior distributions selected for this analysis and the sensitivity to resulting conclusions.