Leveraging Bayesian Techniques in DOE Model Prediction and Simulation to Enhance Decision-Making in the Context of Large Molecule Process Characterization in the Pharmaceutical Setting

Authors:
Yang Cao, Jyh-Ming Shoung
Quantitative Sciences & Clinical Pharmacology, Johnson & Johnson Innovative Medicine

Abstract:
The presentation focuses on the application of Bayesian techniques specifically within the pharmaceutical industry for process characterization of large molecules. This includes assessing criticality of the parameters and evaluating the Proven Acceptable Range (PAR). To bridge the gap between statistical impact and practical impact caused by a specific parameter within the design space, an effect-to-noise ratio based on the Design of Experiments (DOE) model is proposed, aiding in determining parameter criticality. Bayesian methods are employed to enhance the estimation of the effect-to-noise ratio, taking into account model uncertainty. Furthermore, Bayesian methods are applied in model-based simulations to assist in evaluating the Proven Acceptable Ranges (PARs).