FDA Bayesian Statistics Guidance for Medical Device Clinical Trials—Application to Process Validation

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On February 5, 2010, the US Food and Drug Administration Center for Devices and Radiological Health and Center for Biologics Evaluation and Research issued a final Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials. The guidance furthers FDA’s efforts to foster innovation, efficiency, and sound science in the industry. The guidance joins, after two and a half centuries, two seminal concepts: scientifically rigorous prospective clinical trials and Bayes rule. The appearance of the guidance represents a paradigm shift in allowing the objective use of data-based prior...

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