

Quality by Design (QbD) is a new product development paradigm currently being adopted by both the biopharmaceutical industry and regulatory agencies. QbD achieves product quality through greater understanding of the product and manufacturing process. Key to this is to leverage statistical principles and methods.

Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing is the first book that presents statistical advances in the implementation of QbD in the pharmaceutical industry. Drawing from the author's extensive experience in drug R&D, regulatory submissions, and statistical research, the book blends biopharmaceutical R&D issues, regulatory requirements, and statistical solutions, all based on the most current information and innovations. A comprehensive resource, it combines in-depth explanations of advanced statistical methods with real-world case examples.

Features

- Analytical method validation based on testing "fit for intended purpose" hypotheses
- Applications of Bayesian methods and generalized pivotal quantity analysis for parallelism testing and validation of assay linearity
- Risk assessment of residual host cell DNA through statistical modeling
- Risk-based approach to bioburden testing
- Statistical evaluations of viral clearance
- Establishment of multivariate specifications for correlated quality attributes
- Continued process validation and verification
- Development of effective environmental monitoring programs
- The latest advances in stability study design and analysis
- Comprehensive statistical tools for OOS and OOT investigations
- Novel use of statistics to influence industry practice and regulatory thinking
- New role for the non-clinical biostatistician in biopharmaceutical

Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing is a single source of reference for statisticians and scientists in the biopharmaceutical industry, academia, and regulatory agencies.

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