

?Application of Probability of Passing Multiple Stage Tests in Benchmarking and Validation of Processes

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Quality, safety, and efficacy must be designed and built into the product. Quality cannot be inspected or tested into the product. Each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all quality and design specifications. This article will discuss the scientific aspect of the last QA principle mentioned above and describe how to demonstrate the probability of meeting the product specifications, for multiple stage tests, for future quality control (QC) samples using process optimization or validation test results. Demonstrating...

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