Don’t Bet on Quality by Chance Part I: Taking the Guesswork Out of Validation

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QbD is a systematic approach to product and process design and development. The goal of QbD is to enhance robustness by building quality into the manufacturing process rather than testing it in. It also provides a structured framework for innovation and continuous improvement. “Robustness is the ability of the process to tolerate the expected variability in raw materials, operating conditions, process equipment, environmental conditions, and human factors.” (5) A process is considered robust if it can consistently meet performance requirements even when it is run under worst-case operational...