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Practices, January. 2001, U.S. Department of Health and Human Services, Food and Drug

The “Process Validation: General Principles and Practices” guidance published in 2011 advises that process validation should extend to activities occurring across the life cycle of a product.(6) It specifies that a life cycle approach to process validation involves three phases of activities: Stage 1 – Process Design Stage 2 – Process Qualification (PQ) Stage 3 – Continued Process ...

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In January 2011, the U.S. Food and Drug Administration published new process validation guidance for pharmaceutical processes. The new guidance debunks the long-held industry notion that three consecutive validation batches or runs are all that are required to demonstrate that a process is operating in a validated state. Instead, the new guidance now emphasizes that the level of monitoring ...

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