

Expectations for Validated Processes

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Process understanding includes all scientific and technical work conducted in support of validation conformance batches and subsequent routine manufacturing and monitoring. This work includes the lab-scale, pilot-scale, and commercial-scale studies conducted to establish the design space within which the process can successfully operate during routine commercial manufacturing. Process understanding must include an understanding and control of variable input factors (materials, people, etc.) affecting the process, as well as technology transfer from pilot scale to commercial scale processing. The...

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