Process Performance—Conformance Lots

By , , , , May 23, 2013 1:51 pm EDT

Recent documents and discussions have emphasized a comprehensive and integrated approach to the validation of manufacturing processes—the lifecycle approach to process validation. This approach includes process understanding derived from laboratory studies and process development history, confirmatory process performance at commercial scale using specified process parameter values (conformance lots), and maintenance of the validated state during routine manufacturing by ongoing process monitoring. When the process is understood and process parameters are decided, conformance lot manufacturing...

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