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FDA 2011 Process Validation Guidance: Process Validation Revisited

By **Cliff Campbell** , **Paula Katz** **Jan 10, 2013 9:12 pm EST**

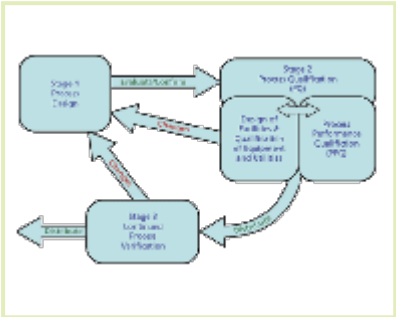

Figure 1: Stages of process validation.

This article is based on a technical training seminar presented to United States Food and Drug Administration policy advisors, management, and field staff in Silver Spring, Maryland, in May 2012. It summarizes the regulatory drivers that led to the publication of FDA's 2011 Process Validation Guidance for industry. In particular, the article emphasizes that process validation is a meaningful scientific endeavor that strives to ensure process control and product quality rather than a discrete and isolated activity. The article proceeds to describe practical steps that product manufacturers can...

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