

## PQ Forum: FDA Lifecycle Approach to Process Validation—What, Why, and How?



**Paul L. Pluta**

By

**May 10, 2013 4:36 pm EDT**

The US Food and Drug Administration issued Process Validation: General Principles and Practices in January 2011, which has given widespread visibility to the lifecycle approach concept. The process validation guidance integrates strategy and approaches to provide a comprehensive approach to validation. Three stages in the lifecycle approach are identified. The lifecycle concept links development, validation performance, and product or process maintenance in a state of control during routine commercial production. Understanding the sources of variation and control of variation commensurate...

---

**Source URL:** <http://www.ivtnetwork.com/article/pq-forum-fda-lifecycle-approach-process-validation%E2%80%94what-why-and-how>