Guidance Number: 029

The key differences between a process using CQV and the conventional approach are given below.

Aspect	Conventional Process Validation	CQV
Manufacturing process	Fixed: validation on a small number of initial full scale batches. Focus on reproducibility.	Adjustable / flexible within design space. Continuous quality verification within design space. Focus on control strategy and robustness.
Process controls	In process tests primarily for "go/no go" decisions. Analysis typically has slow response compared to process timeline.	Monitoring, measuring, analyzing and adjusting (if necessary) the critical aspects of manufacturing steps /unit operations in real time.
Control strategy	Product quality controlled primarily by in-process and end product testing.	Some quality controls shifted upstream, with possibility of real-time release or reduced end-product testing.
Validation Approach	Typically prospective for a new process	May be concurrent for a new process

Figure 1: The Four Elements of CQV

The sequence of documentation needed to support implementation of CQV is summarized in the flowchart in Appendix 1, and each are further described below.

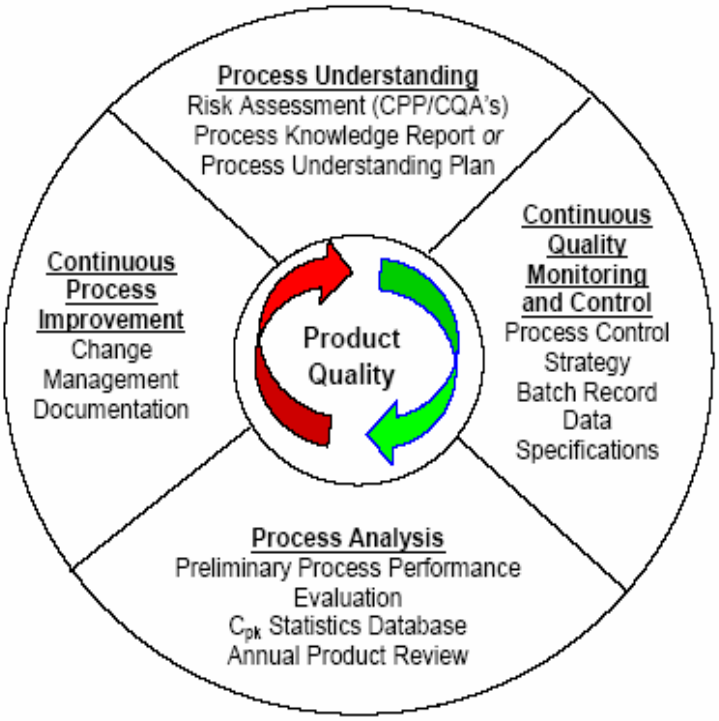

Figure 1
The Four Elements of CQV