Summary - Documentation to Support Continuous Quality Verification

Continuous Quality Verification (CQV) is an alternative approach to process validation. One of the primary differences for CQV compared to a conventional discrete, 3-batch process validation approach is that the process is continually monitored, evaluated, and adjusted (when necessary) to achieve defined Critical Quality Attributes (CQAs) using validated in-process measurements, tests, controls, and process end points.

The CQV approach to process validation may be applied to both new and legacy processes when the necessary information is available. It requires a good understanding of the process and a process control strategy that ensures repeatable and robust performance of the process.

Differences between processes implementing CQV and those following a conventional approach:

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

1. Process Understanding:

Process design documentation is a pre-requisite for CQV and should include the following:

a) *Documented summary of scientific understanding of Product and Process(es)*

During process development, the proposed process design is investigated and characterized by experiments, process modelling, etc. Critical Quality Attributes (CQAs) for the product must be defined and documented. Potential Critical Process Parameters (CPPs) to be controlled and monitored in order to achieve CQAs must also be identified whether using a conventional or a CQV approach