The responsibility for providing the data will depend on the stage of the product lifecycle; for example, Research and Development (R&D) should provide documentation (for example, a Process Knowledge Report or Process Understanding Plan) for a new process, whereas for a legacy process, commercial batch data and any experimental data may be provided by the site Technical Services or Production Support groups.

b) *Documented Review of revised Risk Assessment review*

A review of the Risk Assessment defining the final CPPs and CQAs should be conducted once the specific site and equipment where the process will be performed are identified. In addition to accepting the risk assessment justifying the CPPs and CQAs, the review should include consideration of:

- The level of process knowledge available to support the proposed commercial scale (e.g. scalability studies or data at full scale)

- The impact of equipment capabilities on the CPPs that have been identified (e.g. comparison of expected normal operating ranges with proven acceptable ranges)

This revised risk assessment is recommended for any process, whether using CQV or a conventional process validation approach. This revised risk assessment is site-oriented, and therefore, where practical, personnel from the assigned manufacturing site(s) (for example, site technical services, site production support) should be involved in the preparation. It should be finalized before the approval of the Process Control Strategy as it is a key input to the strategy.

c) *Process Capability Studies*

It is recommended that CQV is only applied to processes that have been demonstrated to be both capable and stable. The data for this evaluation may also be used for the Preliminary Performance Evaluation (see below). Right-First-Times (RFT) tools should be used to evaluate the process; the type of tool used may depend on the amount of data available.

For legacy processes where implementation of CQV is being considered, the Right First Time initiative on Product Based Process Capability may provide an indication of the process performance and therefore its suitability for CQV implementation.

2. Continuous Quality Monitoring & Control.

a) *Process Control Strategy*

This document defines the process control strategy proposed for routine manufacture, describing the scheme for monitoring, measuring, analysing and adjusting (when necessary) the critical aspects of manufacturing steps / unit operations, and how this scheme will ensure control of product quality. Real-or near-time adjustment of the process, when necessary, is a key element of CQV.