

4.5.6 Use of Corrective Action Tracking or CAPA Systems During C&Q

Ensuring that corrective and preventive actions are recorded, reviewed, and approved is a key feature of any Quality Management System. In the context of a project life cycle, maintaining traceability of corrective actions required and executed across the various activities is fundamental to the successful achievement of acceptance and release for commercial manufacture and any subsequent regulatory reviews or inspection.

Pharmaceutical companies use “Corrective And Preventative Action” (CAPA) systems to formally investigate and track non-conformances and deviations with potential to impact product quality. Organizations may use these site based CAPA systems to manage non-conformances arising from C&Q events. Organizations may prefer to use C&Q punch lists to follow up with issues in C&Q. Points to consider when making decisions about the use of CAPA systems include:

- When performed prospectively, C&Q “failures” cannot impact product in the field, since the facility or system in question has not been accepted or released for commercial use.
- CAPA systems can be “loaded up” with minor or trivial C&Q “non conformances” that only serve to obscure the quality-critical events that the CAPA systems were intended to track.

The recommendation of this Guide is to use formal CAPA systems with discretion for tracking IQ, OQ, and PQ issues. Questions such as those listed may be used to separate items that can be documented, tracked, and closed in project documentation versus those that should be investigated and tracked per an organization’s CAPA procedures:

1. Does the event in question have the potential to impact any facilities or systems already in production use or product that has been released?
2. Does the event in question have the potential to be “systemic” – that is – does it represent a potential quality system deficiency (such as inadequate training) that can or will result in similar events in the future?
3. Does the event in question require a documented investigation to determine cause and/or necessary corrective action?

Where the answers to these questions are all “no,” the recommendation is to document the correction and closure of issues in project specific documentation such as test reports, IQ/OQ summaries, etc. Approval of these documents by the Quality Unit at acceptance and release can constitute acceptance of the “non-conformance” documentation as well. For further information on C&Q non-conformances, see Chapter 2 of this Guide.

4.6 Supplier Issues and Use of Supplier Documentation

The discussion of supplier documentation relates to the use of verification evidence, not the supplier selection process. The choice of suppliers is out of the scope of this Guide. Supplier assessments discussed may be integrated into a supplier selection team, or comprise a standalone activity for C&Q planning purposes.

The use of supplier documentation to avoid repeated and unnecessary verification activities has no direct connection to QRM or a risk-based C&Q approach. It can allow GMP compliance to be achieved at a reduced cost and in less time, which may indirectly contribute to better product quality when these resources are used on other quality-critical activities.

The use of supplier documentation for qualification purposes requires that the level of effort and formality is commensurate with the level of product quality and patient safety. The Quality Unit should review the supplier assessment and confirm the extent to which the supplier’s documentation package may be used to support verification of suitability for intended use. This review and confirmation should be conducted as early as possible.

4.6.1 Supplier Assessment

A pre-qualification or supplier assessment should be performed to assess the robustness of a supplier's QMS. This is intended to provide insight into the strengths and weaknesses of the supplier capability and provide an opportunity to align, or if necessary, impose additional procedures or controls.

A risk-based approach should be taken in determining the project-specific supplier assessment (and qualification where applicable) strategy.

Items to be considered include:

- supplier technical capability and project management capabilities, according to previous experiences
- prior knowledge and experience of supplier according to references
- supplier QMS (if any) and its application in daily work
- supplier application of GEP or equivalent practices
- intended use of supplied equipment or facility
- complexity and criticality of supplied equipment or facility
- novelty of equipment and supplier's ability to verify function
- intended (C&Q project) use of supplier data and information

In general, the higher the degree of utilization of supplier data intended to be used to verify Critical Aspects (and the relative criticality of those aspects), the greater the level of formality that should be placed on the supplier assessment. The Quality Unit should approve verification evidence for Critical Aspects and consultation to assure acceptability is recommended.

4.6.2 Supplier Qualification Strategies

There are several approaches for conducting supplier evaluations,³ e.g.:

- Supplier self assessment using a standardized supplier assessment template or questionnaire
- On site assessment by an SME or assessment team
- Waiver of any project-generated formal assessment may be granted based on a supplier's current qualification status, use history, previous audit, lack of criticality of supplier supplied information, or other documented and Quality Unit approved justification.

The decisions and rationale for the approach taken can be documented and approved through the mechanism of the C&Q Plan or as a standalone activity. This may be part of an owner organization's QMS procedures and routine practices.

³ E.g., ISPE GAMP® Guidance (References 8 and 17, Appendix 5).

4.6.3 Supplier Training

In addition to the communication of project and quality requirements, training should be provided to supplier personnel. Such training requirements should be identified during the supplier assessment. Key areas of training may include:

- application of the end user's QMS requirements in their daily work
- training on GMP as applicable
- importance and maintenance of training records
- documentation version control
- acceptable documentation practices and procedures
- engineering Change Management or project procedures (for mechanical and automation, including software)
- non-conformance and deviation management procedures
- owner's site specific safety, quality, and business restrictions and requirements (for on-site supplier personnel)
- specialist task training

Appropriate training for team members taking over special roles such as facilitator of risk assessments, SME reviews, tank entry, etc. should be carefully planned and scheduled to ensure adequate resources that these specialist skills are available to meet project schedules.

4.6.4 Communication of Requirements, Scope and Deliverables

Project teams should ensure that the fundamental project requirements can be communicated effectively to all parties, both internal and external. These requirements should be documented according to Good Document Practice and subject to appropriate revision control and change management. In addition to the overall project requirements specific items, as a minimum, should be communicated to third parties/suppliers involved in the project, including:

1. Their specific scope of work
2. The specific deliverables, including testing and documentation, included in their scope of work
3. The Quality Assurance requirements for their work and deliverables
4. The Project Controls which will apply
5. The schedule of deliverables – including documentation deliverables and lead times for review and update.

Depending on the size of the project, these may be in a single document or detailed in several project plans, procedures, or specifications. Confirmation should be obtained that the message has been understood and provision made in the schedule for dialogue and/or meetings to provide clarification and confirm comprehension.

From a project risk perspective and to help to assure that quality is "built" in at the outset, supervision, inspections, or surveillance should be arranged of the scope of work and associated deliverables across the life cycle.

4.6.5 Use of Non-GMP Suppliers

The use of assessment, quality assurance plans, and/or supplier quality plans provide a means either to accept or reject a supplier, or to identify where additional resources should be applied to ensure success. Suppliers may not operate within a GMP environment for most of their products and services to customers. Maintenance of a “Quality Management System” may be an unfamiliar or informal practice.

Deficiencies should be recognized early and appropriate support measures established to help to deliver the necessary requirements.

Where deficiencies are identified, additional controls and resources should be applied as early as possible. The supplier needs to support this approach and their agreement should be obtained. Additional control measures, designed to mitigate the risks presented, may include:

- supplier training and guidance
- additional review and approval
- additional auditing of the supplier
- attending/witnessing critical steps in design, fabrication, and testing
- support by third party service providers
- embedding customer personnel within the supplier’s organization for the duration of critical phases of the design, fabrication, and testing
- additional owner testing in C&Q Plans to compensate for an inability to rely on supplier generated test documentation