

Quality Plans For Pharmaceuticals and Healthcare Part 2: Adding ‘Quality’ Into Projects



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INTRODUCTION

In the first article this series we looked at how a Quality Plan can be useful for an organization and the types of applications that a Quality Plan can be used for and objectives that a typical Quality Plan sets out to achieve. In this article, the quality-based requirements for projects that appear within a Quality Plan are considered in terms of their application to quality management systems. This means considering project quality management, a function that encompasses the processes and activities that are used to figure out and achieve the quality of the deliverables of a project.

This article forms part of a three-part series:

- Part 1 – Quality Plan Purpose and Scope
- Part 2 - Adding ‘quality’ into projects
- Part 3 - Quality-based structure of projects

This article explores how ‘quality’ can be maintained for each project within a Quality Plan, from design through to execution.

PROJECTS WITHIN THE QUALITY PLAN

Projects within the Quality Plan

A project is a unique process undertaken to achieve an objective consisting of a set of coordinated and controlled activities with start and finish dates. These activities will conform to specific requirements, including the identification and monitoring of constraints of time, cost, and resources. It is recognized that in some projects the objectives and scope are updated, and the product or service characteristics defined progressively as the project proceeds. While this understanding is fairly well-established, what additional considerations are required reprojects within the context of the Quality Plan?

Projects undertaken within an organization relating to GxP should have the following quality-based structure (based on ISO 10006 recommendations) (1):

- Embedding quality management into projects.
- Connecting projects to quality management systems.

These elements are clarified below.

Quality Management In Projects:

- Quality management systems in projects.
- Management responsibility in projects.
 - Here the organization should ensure that the planning, organizing, monitoring, controlling, and reporting of all aspects of a project and the motivation of all those involved in it to achieve the project objectives come under management responsibilities.
 - Each company should put in place organizational structures, resources, schedule, budget, risk management, environmental management, health and safety management, and security management as appropriate for each project.
- Resource management in projects.
- Product/service realization in projects.
- Measurement, analysis, and improvement in projects.

Quality Management Systems In Projects

Adding management to quality systems (as defined in ISO 9001) (3) produces the following:

- Project characteristics.
- Quality management principles in projects.
- Project quality management processes.
 - Each firm should ensure that division of the project life cycle occurs, where a project is divided into manageable sets of activities, such as conception, development, realization, and termination.
- A quality plan for each project.
 - Each company should ensure that a plan is in place for each project, including the specification of the actions, responsibilities, and associated resources to be applied to a specific objective.

For each project run that has a relationship to GxP, the following quality aspects apply:

- Defining objectives of the system and processes necessary to achieve them.
- Establishing authority, responsibility, and accountability for managing processes and the project.
- Understanding a firm's capabilities and determining the resource constraints prior to action.
- Determining process interdependencies and analyze the effect of modifications to individual processes on the system as a whole.
- Managing processes and their interrelations as a system to achieve an organization's quality objectives effectively and efficiently.
- Ensuring the necessary information is available to operate and improve each organization's processes and to monitor, analyze and evaluate the performance of each project.
- Managing risks that can affect outputs of the processes and projects (including wider risks that could impact upon the PQMS).

In addition, each project should adhere to quality by design principles. ICH Q8 defines design space from the concept that quality cannot be tested into product but has to be built in by design. A further factor of importance is that data integrity is paramount to support the Quality Plan and those engaging in projects within the plan must foster data integrity assurance at all levels and during data lifecycle.

GOVERNANCE

Senior management within a company should have processes in place relating to strategic planning, establishing policies, setting objectives, ensuring , communication, ensuring availability of resources for the company's quality objectives and desired outcomes and for management reviews. In addition, there are:

- Processes for managing resources: This includes all the processes that are necessary to provide the resources needed for the quality objectives and desired outcomes.
- Realization processes: Including all processes that provide the desired outcomes for the company.
- Measurement, analysis, and improvement processes: These include the processes needed to measure and gather data for performance analysis and improvement of effectiveness and efficiency. Through this a company should endeavor to:
 - Measures, monitors, audits, conducts performance analysis, runs improvement processes (like corrective and preventive actions).

KEEPING ON TOP OF THE QUALITY PLAN

To ensure that the Quality Plan and its associated projects remains up to date it should connect to processes of continuous improved; be measurable through appropriate metrics; be compliant (through auditing); and should involve people through connecting the aims and values to the organization's quality culture. In terms of what these mean:

Continuous Improvement

A permanent feature of the Quality Plan is continuous improvement. This ensures each company seeks to improve its quality management system. This includes developing the necessary amount of documentation needed to show the effective planning, operation, control and continual improvement of its quality management

system and its processes.

Metrics and Auditing

An organization should assess quality through an assessment of performance metrics (delivered by tiered meetings) and by auditing. Auditing assess GxPs through system audits of suppliers and internally, through a local ownership program. It is useful to define audits (based on ISO 19011) (2) as systematic, independent, and documented processes for obtaining objective evidence and evaluating this evidence to determine the extent to which the audit criteria are fulfilled.

HUMAN RESOURCES AND PEOPLE DEVELOPMENT

Each company should recognize that people are essential to its operations and that its performance is dependent upon how people's competences are used at work. This can be aided by developing competence management and people development at the organizational, team, group and individual levels are required for organizations to be successful. By people development, this concerns encouraging personnel to acquire new or advanced competencies by creating learning and training opportunities together with ensuring circumstances are created so that these can be deployed.

In addition, quality concerns should be built into the hiring process where the company will ideally consider both value alignment and skills relevant to specific roles.

Training is an essential feature within any firm, and this requires quality input at all levels. Central to training is where people development is a core part of competence management and competent people will require development. These two constructs are inter-related. This is supplemented by GxP training and job competency-based training. Specialist in training, in line with EU GMP Annex 1, requires a focus on microbiology and engineering principles.

QUALITY CULTURE

Quality culture is the mindset and behavior to consistently perform the right things in the design and execution of the quality management principles right first time. This is through an environment where employees can hear, see, and feel quality all around them. Each organization's quality culture is critical for the successful execution of the projects within this Quality Plan. The firm should continuously seek to embed a quality culture, which includes the following elements:

- Patient and customer focus.
- Leadership (ensuring a unified direction from strong leadership to ensure that everyone understands what the goals are).
- Seek the engagement of people (seeking a competent, empowered and engaged workforce at BPL).
- Process approach, including the Pharmaceutical Quality System.
- Seeking right-first time through the one-best-way.
- Seeking continuous improvement.
- Ensuring critical, scientific, and evidence-based decision making.
- Developing relationship management (this means seeking to manage its relationships with all of its interested parties to optimize their impact on its performance, including supplier and partner networks and with regulatory authorities).

This is underpinned by:

- Quality concerns compliance and the collective pursuit of excellence.
- Quality is both a technical discipline and "the best way to get things done" and something of relevance to all.
- Quality must be accessible to all.
- Quality professionals are committed to change.

One means to develop a quality culture is through the following process (as shown in Figure 1):

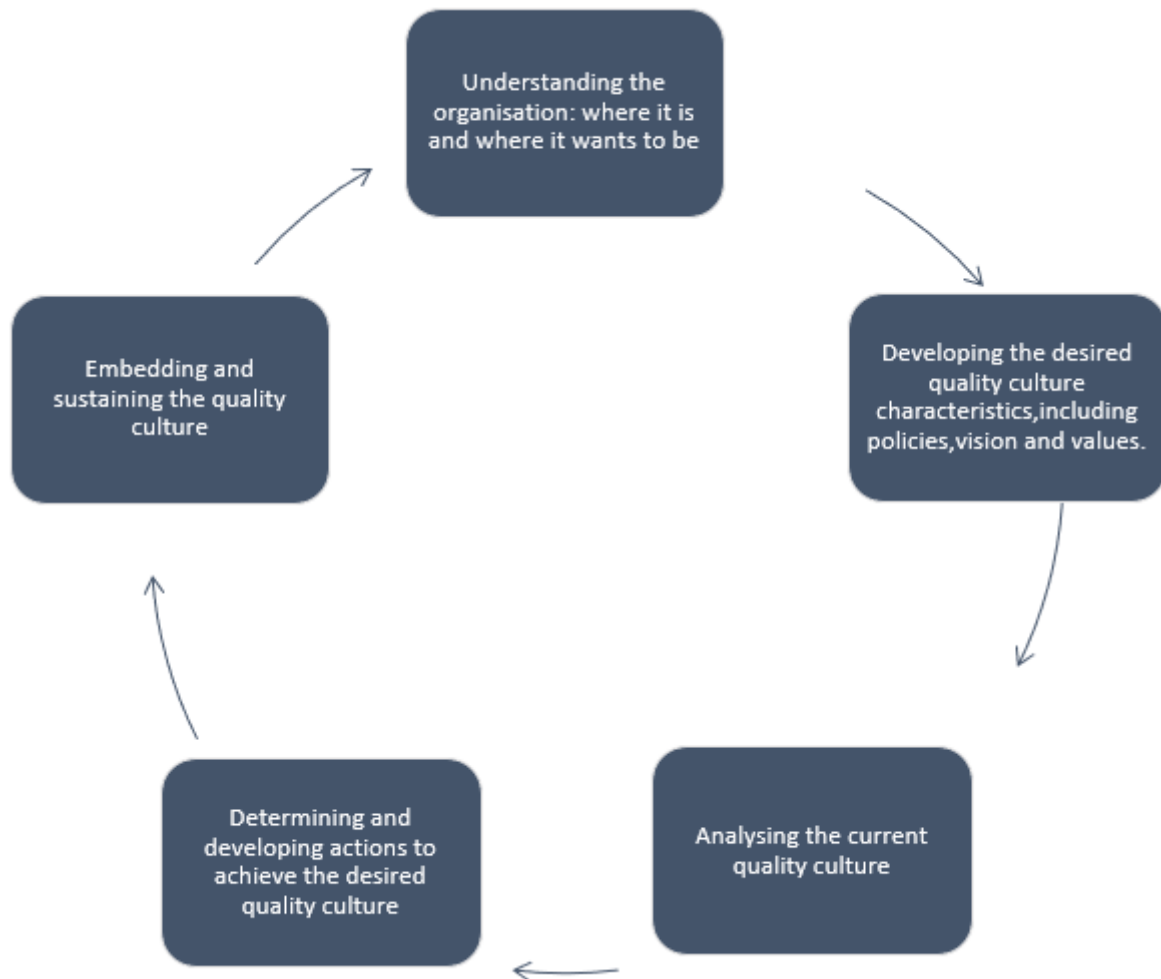


Figure 1: Schematic showing how a quality culture can be developed

The framework of actions for the quality culture is cyclical and continuous. This ensures that quality culture continuously supported the delivery of the quality policy and objectives and supports the delivery of products and services that meet the needs and expectations of patients, regulators, and healthcare professionals.

SUMMARY

This article, the second of a three-part series, has looked at embedding elements of quality into a Quality Plan through connecting the plan to the quality system, to continuous improvement initiatives, and through the organization's quality culture. In doing so, greater success for developing and executing the projects within the plan should be the result.

REFERENCES

1. ISO 10006:2017 Quality management — Guidelines for quality management in projects: <https://www.iso.org/standard/70376.html>
2. ISO 19011:2018 Guidelines for auditing management systems: <https://www.iso.org/standard/70017.html>
3. ISO 9001:2015 for Small Enterprises - What to do? (ISO guidance publication, issued in 2016): https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/iso_9001_2015_for_small_enterprises-preview.pdf