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Published on *IVT Network* (http://www.ivtnetwork.com)

# Quality Plans For Pharmaceuticals and Healthcare Part 3: Quality-Based Structure of Projects

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**Oct 25, 2021 7:00 am EDT**

## INTRODUCTION

When a project with a quality focus is devised it should connect to a Quality Plan and to the quality management system. The optimal way to ensure this connection is effective is to have defined structure. This article looks at the structure of a quality-based project by providing an anatomical breakdown of the core elements.
This article is one 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

Well-designed documentation and an effective structure can ensure that a project runs effectively, from both the reliability, financial, and quality perspectives. This article begins with the steps to incorporate a project within the quality plan and then considers the structural elements of effective project documentation.

## PLACING A PROJECT WITHIN THE QUALITY PLAN

In terms of how to put together a project component with the Quality Plan, these can be constructed and presented within the following framework (as per ISO 9001 recommendations) (1):

- Goals/objectives: This can include specifications, cycle time, materials, and cost. Depending on how advanced the project is, this can represent either:
- A statement of need: This is the first attempt to describe the requirements, before it has been decided that a project is merited or what form such a project might take.
- A project brief : This is designed to provide sufficient information about the project.
- Process steps or procedures to be developed.
- Distribution of responsibilities: Who does what and when?
- Standards: What are the practices and procedures that need to be applied?
- Testing requirements as required.
- Change/modifications documentation procedure: The means to track changes to the project or process.
- Quality process measurement: A way to measure the value of the project.
- Other actions as needed to meet the objectives.

With this established the following best practice aspects can help to develop an effective project with clear and attainable goals. This requires a documented and well-structured approach.

**Structuring The Project Through Effective Documentation**

In terms of an effective structure for each plan, the core part of this article looks at the important documented elements from a quality perspective.

**Purpose**

Each project within the Quality Plan should open with a clear objective. This defines the processes and practices to be adopted by the specific project, in order to provide assurance that all works are managed in such a way that they are delivered to the standard required by and that there is adequate evidence to provide assurance that that standard has been achieved. The objectives must be relevant to the project, reflect the requirements of the organization, provide opportunities for improvement, possibly tied to key process indicators

To support this, the overall Quality Plan can define the policies, objectives and plans for completing all aspects of the works. The project element should contain a list of the applicable procedures, work instructions, and other relevant documentation.

**Scope**

Each project should have a specific scope and a mechanism by which adjustments can be assessed, through an agree process, to ensure that unauthorized expansion or ‘scope creep’ does not occur.

**Context**

A section on the context within which a given project is being conducted is useful. This could be following an audit or in reference to a GxP gap. This section should provide a reasonably detailed description of the project, so as to begin to provide an understanding of the context of the works and the business environment in which it is being conducted.

**Interested Parties**

This part of the plan spells out the stakeholders involved with the project, and functions that are directly involved with delivering the project. Typically, stakeholders could include, among others,

- Those responsible for managing risk.
- Those evaluating effectiveness of risk management.
- Those developing procedures.
- Those operating procedures.
- Those affected if risk materializes or who may present a risk themselves
    - Clients.
    - Supply chain.
    - Sometimes regulators.

**Risks**

It is important that the risks associated with each project are presented, together with the manner in which they were arrived, and updated as the project progresses. The section also enables any mitigations to be discussed.

An appropriate risk template should be used, such as a failure mode and effect analysis (FMEA). This can list the interested parties, the issues they present and the risks that each of these issues may have on the successful completion of the works. The risks can be allocated a probability of occurrence, a potential for damage or enhancement and a probability that the risk will not be discovered. The risks can then be ranged by importance and suitable treatment defined. Importantly, the project manager can decide how risk-tolerant the specific project is.

The responses to each risk may include:

- Avoid (such as ‘do something else’).
- Remove source.
- Change the likelihood.
- Change the consequences.
- Share the risk (potentially by collaborative working).
- Retain the risk by decision and manage (forming the basis for developing procedures, determining monitoring and so on).
- Taking the risk completely away.

*ISO 9001:2015,* requires that (1):

- A Quality Plan contains criteria for successful management of the risks.
- The Plan provides assurance that the quality management system can achieve its intended goal.
- Prevents or reduces undesired effects.
- Achieves continual improvement.

**Quality Policy Statement**

This section represents a commitment to meeting the organization’s expectations by efficiently delivering all requirements right first time. There can also be a link to the Quality Management System and the assurance that the project will provide a safe and efficient delivery to schedule and budget (2). To do this, the project needs to implement, maintain, and control an efficient and effective quality management system in compliance with the requirements of the contract and with ISO 9001:2015 (1). Furthermore, all services that are supplied by the

project need to comply with all professional and legislative standards (according to the applicable GxP) and requirements and shall be provided by staff known to have the correct competencies to undertake the tasks allotted to them.
The quality policy aspect can also detail and maintain an appropriate level of communication, especially where quality service is important.

**Documented Systems**

The project under review must link into the wider Quality Plan and to a project execution plan. This associated document will define the approach that the project as a whole take towards executing the project. This will extend to the structure of the program and the processes by which it will be delivered. Documents must also cover details relating to the assurance that the project is being properly and correctly implemented and that suitable evidence is provided on a timely basis in support of delivery.
Appropriate good document practices include:

- Numbering.
- Revision numbering.
- Checking and approval systems.
- Status of documents, such as 'for construction', or 'for information'.
- How changes are recorded and highlighted.
- Templates, such as document titles and drawing title blocks.
- Formatting (page sizes and orientation, fonts, and font sizes etc.).
- Systems for storing and issuing documents (distribution matrix).
- Control of externally created documents.

To this can be added detail of the media used to store the records (hard and/or soft copy) and the precautions to be taken to make certain that they will remain legible and retrievable, together with the requirements for ensuring that the records are protected from electronic or human intrusion. There should also be controls over the receipt of documented information of external origin, such as client and sub-contractor documentation, national and international standards and working documents provided by other parts of the project. Furthermore, control must be in place to cover any changes to documented information.
Where an Electronic Document Management System is used to control documents, the manner in which documents are to be entered, defined, and retrieved, together with any limitations of access, needs to be defined.
As indicated earlier, there also needs to be procedures and specific work instructions, where these are essential to provide additional information to enable implementation of a particular procedure. Typically, procedures are prepared for general use and made available within an electronic document management system (also some facilities continue to operate paper-based systems).
Connected to the Quality Plan, for each project the process concerning how to define the nature and root cause of the nonconformity as part of a formally documented records, together with the results of the corrective and preventive actions taken, successful or otherwise, needs to be explained.
The organization should make sure that documents and records supporting regulated activities are issued, managed, controlled and archived in a way to accurately reflect the complete history of the organization’s products and services throughout their lifecycle.

**Accountability and Responsibility**

For each project it must be clear, for each member of the team who has responsibility for delivering all or part of the works. This is typically arranged in in hierarchical order beginning with the most senior. It can also be useful to define the following:

- Authority: what level of authority does this person have within the project? What are the boundaries to that authority? There should be an identified person with authority to stop the job, where there is a real and present risk that the works could be delivered incorrectly to contract, especially where future works may conceal what has been done. This may include authorizing exemptions from the project, although care needs to be taken to confirm that no contractual requirement is waived unintentionally in the process.
- Accountability: Who is the person’s supervisor to whom s/he is accountable for delivering his/her part of the works to quality, cost, and schedule?
- Responsibility: For what part of the works is a given person responsible for delivery to quality, cost, and schedule?

The list of personnel should contain individuals who plan, implement, execute, control and monitor the quality process; all individuals responsible for scheduling the works to so that it is delivered to time and cost; all individuals responsible for delivering communications; individuals responsible for resolving issues that may arise across boundaries between one group and another, internally within the project and externally; individuals responsible for audit, surveillance and other monitoring activities, for reviewing the results of monitoring and for defining and monitoring corrective and preventive action; and an indication of who the senior manager is.

**Data Analysis**

For each project, there should be an explanation as to how data gathered from monitoring and measuring activities is analyzed for trends to provide the information that senior management can use to provide proper control is retained over the project. It is particularly useful to explain how the information is to be presented and the schedule for presentation.

The arrangements should cover reviewing and analyzing the nonconformity, undertaking root cause analysis, and determining if further similar nonconformities could occur. Any action that is needed should address the root cause and prevent recurrence. The arrangements should define how risks and/or opportunities arising from the nonconformity are to be analyzed and leveraged, as well as placing them into the risk register.

**Continuous Improvement**

The data that has been monitored and analyzed, together with information from corrective and preventive action should be used to identify opportunities for improvements. These may be in the form of starting points for continuous improvement projects, or they may be of a “Just Do IT” nature. By linking projects to the Quality Plan, a process needs to describe the processes for dealing with corrective actions and corrective actions, as well as for initializing improvement actions (3).

Inputs into the continuous improvement process can include:

- Lessons learned.
- Analysis of product non-conformance.
- Analysis of process non-conformance.
- Analysis of key performance indicators.
- Analysis of complaints, especially of those from interested parties.
- Output from management review.

The arrangements should also define who is to undertake the analysis and how they are to make any perceived changes to the quality management system.

## SUMMARY

This article, the third in the series, has provided an analysis of the essential elements to include in documentation required to support a project that falls within a Quality Plan. By following the advice, a clear understanding of project objectives can be obtained and these together with the project deliverables can be more closely connected to the quality objectives.

## REFERENCES


1. ISO 9001:2015 Quality management systems — Requirements: https://www.iso.org/standard/62085.html
2. ISO 10005:2018 Quality management — Guidelines for quality plans: https://www.iso.org/standard/70398.html
3. ISO 10006:2017 Quality management — Guidelines for quality management in projects: https://www.iso.org/standard/70376.html


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