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Quality Plans For Pharmaceuticals And Healthcare Part 1: Purpose And Scope

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INTRODUCTION

Many organizations within the pharmaceutical and healthcare space will be developing projects within the quality space. This requires the construction and maintenance of a 'Quality Plan'. But what is the function and purpose of such a document? In this IVT article, the purpose and objectives of the Quality Plan are outlined.
Two further articles explore the construction of a Quality Plan in greater detail, making 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 presents what a Quality Plan is and the process for incorporating projects within the overall Plan structure. At the heart of this is an understanding of the planned and systemic activities implemented in a quality system so that quality requirements for project will be fulfilled.

WHAT IS A QUALITY PLAN?

A Quality Plan is a document that outlines core quality objectives and the current projects being developed to enhance quality within the organization. According to ICH Q10 (1), the Quality Plan is: "Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives."
The plan should form part of the Pharmaceutical Quality Management System (PQMS), with the PQMS representing a company's organizational structure, its planning, processes, resources, and documented information that coalesce to achieve the organization's quality objectives. The PQMS should be treated as a dynamic system that evolves over time through periods of improvement. This Quality Plan represents part of this improvement process. This takes the form of projects.

OBJECTIVES

The objective of a Quality Plan is to adopt a strategic approach to help to enable an organization to remain forward-thinking. This includes developing greater internal efficiencies, meeting current and emerging customer requirements, and adapting to meet changing market conditions. An effective Quality Plan should be risk based (in accordance with Quality Risk Management principles) (2). Risk, in this context, is the level of uncertainty inherent in the PQMS. There will be risks in all systems, processes, and functions. However, Risk-based thinking seeks to ensure that these risks are determined, considered, and controlled throughout the design and use of the PQMS.

MANAGEMENT AND DESIGN

The management of projects within the Quality Plan (based on ISO 9001) concerns (3):

The management process must be conducted within a coherent system of interrelated processes. This requires a holistic approach and a risk-based approach. By a holistic approach, to function effectively, the Quality Plan needs to identify and manage numerous linked activities. Each activity using resources must be managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one of the processes directly forms the input to the next. In this context, the approach to quality is addressed through the systematic management of processes and their interactions to achieve an organization's intended results. This means:

- Engaging with internal stakeholders.
- Understanding processes operated within other organizations (such as customers and external providers).
- Ensuring potentially connected processes interact.
- Future processes operate with BPL's Pharmaceutical Quality Management System.

Through this process, it is often best practice to operate horizontal management thereby crossing the barriers between different functional units and unifying their focus to the main goals of the organization.
By risk based, a systematic risk management process should provide a proactive means to identify, assess, remediate, mitigate, escalate, monitor, review and communicate potential quality risks applicable to products and services, processes, systems and projects. This includes review and escalation of both proactive and reactive risks, as per ICH Q9 (2). Quality risk management facilitates continuous improvement of process performance and product and services quality. Mechanisms, including the establishment of a Site Risk Profile and the escalation of quality alerts. The organization should apply Quality Risk Management in a systematic way to consider risk (the effect of uncertainty) so that risks can be understood and managed appropriately. By applying risk-based thinking to the Quality Plan, this enables the organization to determine the importance of particular issues and plane appropriate actions to manage both risks and opportunities.
For each element of the Quality Plan, risk management is applied to:

- Assess the relative priority.
- To determine the minimum requirements.
- To decide upon the processes required.
- To decide upon the resources required.
- To decide upon the control measures required.
- To consider the type and extent of the monitoring activities.

The risk-based approach extends to risk-based thinking, such as:

- Carrying out preventive action to eliminate potential non-conformities(including elements of the Quality Plan).
- Analyzing any nonconformities that do occur (such as trending deviations and CAPAs).
- Taking action to prevent recurrence that is appropriate for the effects of the non-conformity (such as CAPAs and effectivity actions).

Engagement

A Quality Plan is of little practical value if management do not effectively engage with the workforce. This means focusing on people, training, and communication.

People and resources

For each project within the Quality Plan, the appropriate director needs to decide on the level and form of competence required for each task that is to be undertaken, confirm that members of staff undertaking the work have achieved that level of competence and that there are records available to provide evidence of such. Where there are shortfalls, the organization should provide training or other means to resolve them.
Personnel involved must be made aware of the project and its objectives. In addition, each person involved must understand how their work contributes to the effectiveness of the project and the implications of not conforming to the requirements of the project.

Training and education

It is important that those carrying out a project under the Quality Plan have the necessary skills and competencies to deliver. This extends to all of the information that a member of staff needs to know in order to complete his or her tasks correctly and could include technical information, procedural documents, and briefings.

It is also important that as each project proceeds that organizational knowledge is captured. Such knowledge must be readily retrievable. Organizational knowledge can be derived internally, including from lessons learned and knowledge from experience, and externally, such as that from customers/external providers, attending conferences and academia.

COMMUNICATION

The Quality Plan should state who has is to act as the prime channel of communication with the customer, as well as defining who in each department is to liaise with whom on the Client side, where this is appropriate. This will include providing information about products or services, handing enquiries and orders/contracts, dealing with customer's property, and establishing requirements for contingency actions. The means of communication should be stated, for example, when formal letters are to be used, what records are to be retained of meetings with Clients and how informal approaches are to be handled.

CONCLUSION

The Quality Plan presents an effective way for an organization to clarify, sort, rationalize and plan its quality objectives and also provide a single source from which to distil the key quality objectives organization wide. It is recommended that Quality Plans are reviewed at least once each year. Plans should also be reviewed following a significant change in procedures, processes, or organization, whether generated internally or as a result of external influence.

REFERENCES

1. ICH Q10: 2009 Pharmaceutical Quality System: https://www.fda.gov/media/71553/download
2. ICH Q9: 2003 Quality risk management: http://www.ich.org/LOB/media/MEDIA3562.pdf
3. ISO 9001:2015 Quality management systems — Requirements: https://www.iso.org/standard/62085.html

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