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

Quality Plans for Pharmaceuticals and Healthcare: Checking the Maturity of Your Quality System

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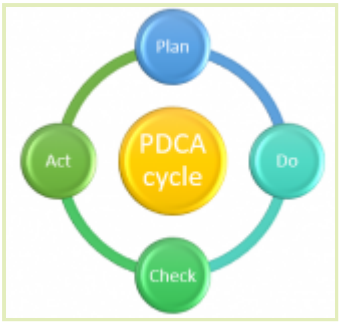
Mar 8, 2022 8:00 am EST



INTRODUCTION

How effective is the Quality System in your organization, be that pharmaceutical or healthcare related? While there is copious advice (not least in regulations) as to how a Quality System can be established, this does not necessarily help with evaluating the effectiveness (or what we might call 'maturity') of the system. A mature Quality System will (1):

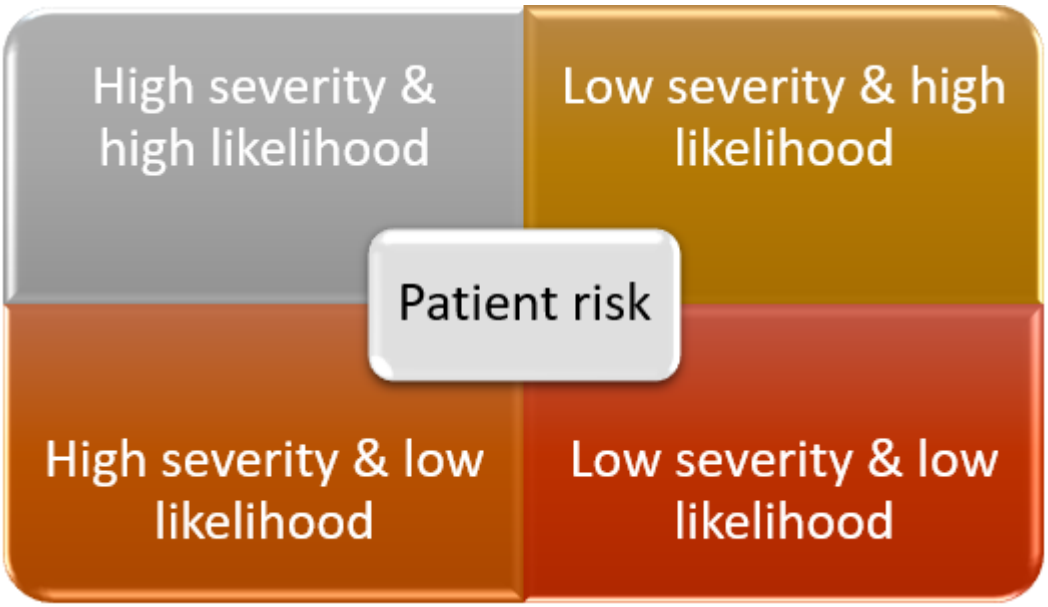
- Achieve product realization.
- Establish and maintain a state of control.
- Facilitate continual improvement.

This article presents some points for consideration when establishing a Quality System, with the idea that the points raised could be used as a checklist for an organization to use on its path towards strengthening and deepening the system.
This article follows on from other IVT articles in the series. These earlier articles are:

1. Quality Plans for Pharmaceuticals and Healthcare Part 1: Purpose and Scope
2. Quality Plans For Pharmaceuticals and Healthcare Part 2: Adding 'Quality' Into Projects
3. Quality Plans For Pharmaceuticals and Healthcare Part 3: Quality-Based Structure of Projects

REVIEW AGAINST CURRENT STANDARDS AND REGULATIONS

The first step in assessing whether the Quality System is fit-for-purpose is to ensure that all written Good Manufacturing Practice (GMP) texts are being adhered to. Should any gaps be identified, these should be raised as corrective actions and tracked (2). In undertaking the gap analysis, it is important to determine the amount of work and resources that will be required to fully adopt the framework. If it arose there were several gaps and a period of time was required to resolve these, then a risk assessment should be undertaken to assess the impact upon the patient and product, in relation to essential areas like contamination and efficacy.
To generate an effective risk assessment use there needs to be a risk management system in place and for personnel to be able to perform risk assessments, which requires the development of suitable risk management skills. Traceability of the risk management system should be through a risk register that is regularly reviewed (3).
A simple high-low matrix can be used, such as:



LEADERSHIP SUPPORT

No Quality System can function effectively without the support of senior management. It is important that senior managers across the organization understand and contribute to the shape and form of the Quality System. In addition, the system must be seen to be 'owned' by everyone within the organization (and not simply by the Quality department). Ensuring that the managers of all functional areas know and understand this is essential for developing this culture.

REVIEW QUALITY POLICY AND QUALITY OBJECTIVES

The quality policy and quality objectives should be regularly reviewed. One way to test the system maturity is to cross check the policy and quality objectives against case studies and then to modify these so that they full represent regulatory expectations in a way that can be understood by employees (4).

Benchmarking can also assist with this process and using the main sections in ICH Q10 is a good place to start:

- Culture of quality.
- Risk based management.
- Management responsibility.
- Management of outsourced activities.
- Product quality monitoring.
- Deviations.
- CAPA.
- Change management.
- Quality improvements.
- Quality management review.

QUALITY SYSTEM TRAINING AND SOLICITING INPUT ON WORKPLAN

Training and education about the Quality System should be part of new starter onboarding and feature as part of refresher training. The periods for re-training and re-assessment may vary according to the nature of the work at a specific site. As a minimum, GMP training would be annual.

A relate area is with encouraging staff to contribute, such as soliciting their feedback and encourage developing a culture of quality and continuous improvement. In order to ensure effective communication and to show the organization is a listening one, senior management should review any work plans or system development based on employee feedback.

ASSESS QUALITY SYSTEM PROCESSES

The effectiveness of different elements of the Quality System process required for delivering quality goals should be regularly assessed. The organization should develop and document the procedures to follow to ensure each process is completed in a consistent and effective manner.

ENSURE STANDARD FORMS AND STANDARD OPERATING PROCEDURES WORK

One of the main issues within human factors is with people not following procedures correctly and invariably this relates to the way the procedure was written or the way it has been rolled out. When deviations occur, the procedural elements should be a focal point and where improvements are identified these should be actioned through documentation updates as a means of aboding recurrence of the issue.

Furthermore, as the Quality System evolves and improves, it is important to create and adjust relevant documents to ensure that they are appropriate.

DEVELOP AND REVIEW PERFORMANCE MEASURES

An important way of assessing the effectiveness of the Quality System is through the development and application of metrics. Performance measures can be used to assess customer satisfaction, deviation rates, change control closures, CAPA effectivity and so on. The types of metrics set, and the target values will need to be readjusted as the organization moves forwards. This should also be the case as the organization achieves improvement.

In designing metrics, these should be geared around a best-practice approach to performance and quality monitoring. The optimal system should be forward looking, systematic and based on data gathered using appropriate tools and analyses.

The review process should consider improvements to manufacturing processes and products and the provision, training, and realignment of resources. It also important to capture and disseminate knowledge, within the review and throughout the organization.

EFFECTIVE DOCUMENTED INFORMATION AND DOCUMENT CONTROL

All documents pertaining to quality (be those within GMP or a system outside of GMP, such as health and safety) should be within a documentation control system. Documents need to be subjected to document control to ensure the latest document is being referred to and kept up to date with regards to any changes. Typically, this will be an electronic document management system, where given the scale of documents generated within a typical organization a digital system is the only way to effectively manage all the Quality System electronic files.

CONDUCT INTERNAL AUDITS

In addition to metrics, auditing is an essential feature of the Quality System. Prior to commencing audits, it is important that personnel are suitably trained in conducting an internal audit. This step will involve establishing a schedule for auditing all components of the program delivery. The focus of these audits is to identify “opportunities for improvement” and make incremental improvements.

REVIEW AUDIT FINDINGS AND CAPAS

A board designed to review audit findings and to track corrective and preventative actions is important to trend and identify actions, as part of the process of rectifying raised issues and putting in robust measures to prevent recurrence.

The objective of having a board is to share findings as well as the proposed actions to be taken. The senior leadership need to be aware of how the Quality System is operating, as well as being actively involved. An example of the way that items are assessed and reviewed is through the cycle of plan-do-check-act. This process is often repeated in an effort to strive for continuous improvement (5).

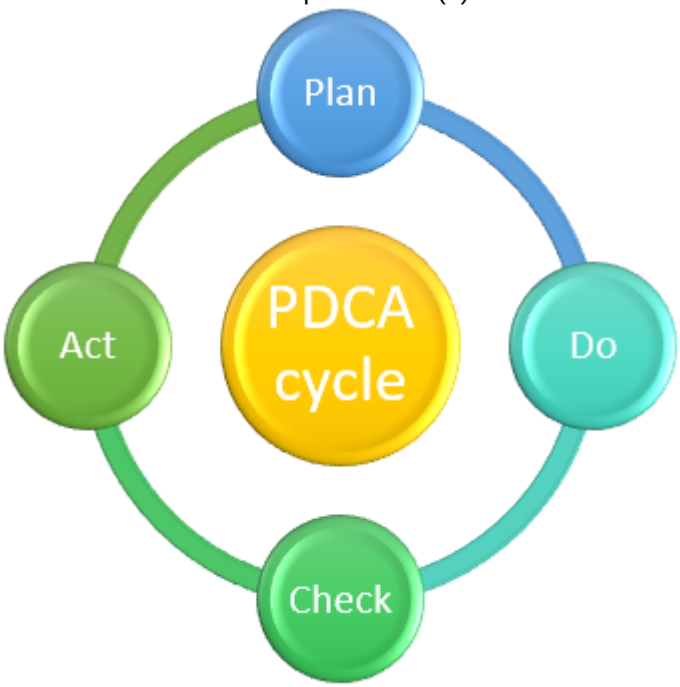


Figure 2: Representation of the iterative plan-do-check-act approach. A fundamental feature of the PDCA process is the cycle itself, so once a hypothesis is confirmed (or negated), executing the cycle again will extend knowledge further.

COMMUNICATE REGULARLY WITH PERSONNEL

It is important to continuously raise awareness within the workforce about the Quality System state and any intended changes. Regular communications with staff on the progress being made reinforces the importance of this effort.

CORRECT NON-CONFORMING ACTIONS

Ensuring the effective correction of non-conforming actions is an important process and while there will be targets (and pressures) to close these, it is important that events are assessed to see if they have happened before and that actions are verified in order to assess their effectiveness.

SYSTEM OF CRISIS MANAGEMENT

While measures should be taken to avoid a major event, issues will occur such as product recalls. Addressing these requires a system of crisis management. This needs to be based on a plan, and the plan should reflect the risk in the business and to ensure the adequate skills, resource, simulation, and review are incorporated.

EFFECTIVE OUTSOURCING

Management responsibilities need to extend to the control and review of any outsourced activities and quality of purchased materials. The pharmaceutical or healthcare company is ultimately responsible to ensure processes are in place to assure the control of outsourced activities and quality of purchased materials. These processes need to incorporate quality risk management.

KEEP UP TO DATE WITH REVISIONS TO REGULATIONS

It is important that regulations are regularly assessed, especially when these occur as guidance notes (which add the ‘current’ into cGMP).

SUMMARY

This article has presented some advice on the assessment of an existing Quality System, as a means to gain an indication of the state of the system and its relative maturity. A mature system will be more robust and resilient and trough this a safer and more efficacious product will be manufactured. In addition, a high performing Quality System allows the organization to bring products to market quicker; establish and maintain a state of control throughout the product lifecycle; and to facilitate continual improvements to products and processes.

REFERENCES

1. Ramakrishna, S., Tian, L., Wang, C.*et al.* (2015). Chapter 3: Quality management systems for medical device manufacture.*Medical Devices: Regulations, Standards and Practices*. Woodhead Publishing Series in Biomaterials. Vol. 103. Elsevier. pp. 49–64
2. Nanda, V. (2016).*Quality Management System Handbook for Product Development Companies*. CRC Press. p. 352
3. Garvey, P., Landsdown, Z. (1998). Risk Matrix: An Approach for Identifying, Assessing and Ranking Program Risks.*Air Force Journal of Logistics*. DIANE Publishing. 22 (1): 18–21
4. Nally, J.D. (2007).*Good Manufacturing Practices for Pharmaceuticals* (6th ed.). CRC Press. p. 424
5. Tague, N. R. (2005) Plan–Do–Study–Act cycle. *The quality toolbox* (2nd ed.). Milwaukee: ASQ Quality Press. pp. 390–392
