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CAPA MANAGEMENT: THE HEART OF PHARMACEUTICAL QUALITY MANAGEMENT SYSTEMS

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ABSTRACT

Business processes are meant to achieve the goals and objectives of the organizations. Business processes must be in command of quality systems to enhance the profit in organization. As far as pharmaceutical organizations are concern the quality management systems plays a vital role in overall growth of organization. Those quality systems are Deviation, Change control, CAPA, Internal Audit, Risk Management, Management Review, Annual product review, Customer Complaints and Recall. Appropriate management of above mentioned quality system is mandatory to be in compliance with National and International Regulatory requirement

The challenge in current situation in Pharmaceutical organization is the management of corrective and preventive action. The prime focus of this research paper is to outline about the importance of CAPA management system that is conglomerating all other quality management systems. The non conformances of different quality systems led to the investigation of root cause. As better these actions from root cause investigation is managed, better would be the regulatory compliance. CAPA is the result of root cause investigation of non conformities of different quality management systems. Once these actions are completed the QMS cycle would be in better position of compliance. In a way CAPA management is working as a Heart which collects the actions from different quality systems and surpass to continuous improvement in organization. A good CAPA Management system will help decision making easier.

Key words: *CAPA, Quality Management System, cGMP, Pharmaceutical organization, Regulatory, Inspection, etc.*

Introduction:

The non compliances or non conformities are bound to happen in working environment; however there are systems that work to minimize or diminish the non compliances. Quality

systems are designed to manage the non compliances in business processes. The very basic purpose is to avoid proactively the discrepancies in business processes of operations. When one cannot manage the discrepancies, it impacts the non compliance of quality management system. Quality management systems include Deviation, Change control, CAPA, Internal Audit, Risk Management, Management Review, Annual product review, Customer Complaints and Recall. Once the non compliances are at quality management system level it goes into reactive mode. To overcome the non compliances, organization has to investigate the root cause to be in compliant with cGMP and regulatory requirements. Here is the active role of CAPA management system comes to gather the actions resulting from investigation and to monitor the progress of actions until mitigation. Effective CAPA management system is a prospect to improve quality culture in the organization. CAPA system is not just to satisfy regulatory requirements, but to facilitate a resolution system for non compliance which indirectly control the "fire fighting" and avoid the business loss.

What is CAPA:

CAPA is Corrective and Preventive actions, however it is much more than just “Corrective actions” and “Preventive actions”. Corrective Action is the action to eliminate the cause of a detected nonconformity or other undesirable situation and Preventive Action is the action to eliminate the cause of a potential nonconformity or other undesirable potential situation. (ICH Q10). CAPA is vital to an organization's regulatory compliance initiatives.

An effective CAPA program will decrease process variation and improve product quality. The source of CAPA is critical to understand, depends on the criticality the priority can be decided. Management support and management review are necessary for an effective CAPA process. CAPA methodology must result in product and process improvements and enhanced product and process understanding.

Challenges of CAPA Management System:

- Improper investigation of the cause resulting from different quality systems.
- Recurring issues because of unstructured fixing of the problems.
- Focusing on remedial action to run the business.
- Insufficient management review on Quality Management System.
- Lack of resources and competency.
- More focus on manufacturing activities for more output.
- More reactive approach than proactive.

Attributes of CAPA Management System:

The main aspects of CAPA management system are assigning the CAPA, monitoring the CAPA progress and the effectiveness check of CAPA.

Assigning the CAPA:

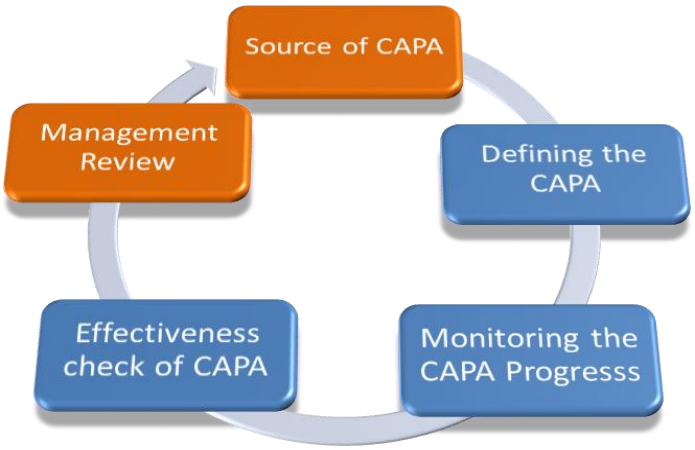
It is the very basic step to mitigate the non compliance issues. One has to identify correct root cause of issue, once the root cause is identified it become easier to assign corrective action and preventive action which will take care of identified issue to avoid recurrence and potential issue to avoid occurrence respectively. Many organizations are failed at this step which invites the recurrence of the same issue again and again. The reason behind the recurrence is improper investigation of non compliance issues. There are various methods or tools that provide correct investigation of issue for example Fish bone analysis, Failure mode effective analysis and 5 Why's etc. Correct follow up of investigation tool will give you correct root cause that contribute assigning the precise and accurate CAPA.

Monitoring the CAPA Progress:

Now days in market various software, tools and techniques are available to monitor the progress of CAPA. The ultimate significance of these software, tools and techniques is to monitor the completion of the defined actions and respect the timelines of those actions. The advanced software like SAP, Trackwise are readily available solution which is easily configured to fit business processes without the need for customization. However some organizations are still using the ERP modules or Spreadsheet to monitor the progress of CAPA. Mitigation of actions and catching the timelines are crucial rather than having the best software or ERP module.

Effectiveness check of CAPA:

It is not always necessary that once the CAPA has been given there will not be recurrence of the issue. The same issue may trigger because of another reason. Effectiveness check of CAPA is essential so as to verify with implemented CAPA, there is compliance, improved control, and reduced risk of recurrence and lower costs through the consolidation of redundant systems. Effectiveness check can be done by revisiting the actions that has been implemented so as to comply the non conformities.



Centralized CAPA Management and Sources of CAPA:

A mature quality management system detects the problems before they occur and then prevent the problems. CAPA is of paramount importance to the FDA. According to FDA documents CAPA accounts for 30-50% of FDA-483 forms issued for non compliance. (PHARMATUTOR-ART-1264)

All the elements of quality management system that are different quality systems to oversight business processes must have their own management systems. Failure of these systems indicates the business processes are not followed. The business processes falls under the Tier 1 which are for different operational activities. For e.g. day in and day out activities of production floor and QC laboratories. The quality systems falls under the Tier 2 that governs the business process. Failure to business processes will definitely fail the quality systems. The CAPA management system governs the Tier 2 to have better control to be in compliance with regulatory and cGMP.

Internal audit management system is verification of compliance by self, so it is very useful for the organization to identify the gaps and mitigate before it is noticed by external regulatory agency. This system is prime source of CAPA and provides the oversight on business processes so that organization can meet cGMP and regulatory requirement. Customer complaint management is crucial to any Pharmaceutical organization as it involves health of customer and reputation and cost of the organization. Therefore the CAPA resulting from the customer complaint has to mitigate on priority. Deviations management is one more source of the CAPA. Deviation system manages the unplanned events which may have occurred due to malfunctioning of the operation, machines etc. Basically deviations are

nothing but the diversion of defined standard procedure. CAPA resulting from deviations are more concerned of FDA inspectors as the deviations are not the usual thing. Change control is another system where planned event are captured, the CAPA resulting from the change control system is to be focused consciously because the change executed has to be verified for its successful implementation. Risk Management is one of the very essential quality systems to run the business successfully. This system provides the futuristic events that may trouble the organization by achieving the strategic goals. So the CAPA resulting from risk management is beneficial to business to avoid the issues proactively. Recall system is also important source of critical CAPA where organization has direct connection with regulatory agencies. What actions need to be taken to avoid the recall because of same cause. Regulatory inspection is one of the major sources of CAPA and has be follow closely to avoid further non compliances. In addition to these sources of CAPA one of the important aspects is the annual product review. In annual product review whatever actions arising need to consider as part of continues improvement of the quality management system.

All the CAPA sources discussed above are the significant for effective quality management system. All the systems are linked to the CAPA for mitigation of gaps or non compliances. CAPA is at the center for controlling the effectiveness of quality management system to drive organizational efficiencies and modernization with respect to compliance status of organization.

Benefits of the Centralized CAPA Management:

- Fulfills the promise of continuous improvement
- Leads to better customer satisfaction and less risk to the public.
- Better use of resources through a structured QA system.
- Facilitate better and more informed decisions by organizations.
- Makes good business and financial sense.
- Increasing organization's compliance quotient.
- A reduction in quality and severity of issues
- More preventive actions over time
- Better designed products/processes.
- Improved customer satisfaction.
- Better business results

In addition to above benefits, the organization is always in a status of compliance and can be said as all time readiness for inspection with proper implementation of CAPA. Implementing a centralize CAPA management system as part of an overall quality management has ultimately reduced costs and enhance the growth of organization.

Conclusion:

The correct implementation of centralized CAPA management system reduces quality issues and organization may reach to goal of zero defects. CAPA management is neither difficult to understand and implement, nor it is difficult to execute except when companies fall short in the follow-up portion and 'closing the loop' of the CAPA.

CAPA system is center of the quality management system where all the actions are narrowed down. Effective collection of these actions resulting from the non compliances of quality system will help organization to avoid non compliances and ultimately reduced the FDA citation. CAPA management system regulates the non compliance by finding out root cause of the issue, defining the actions, following the actions till mitigation, effectiveness of action for continuous improvement. Effectiveness of the actions must undergo to management review which would complete the closed loop of CAPA management system. The centralized CAPA management system must avoid the non-compliances when used with correct approach. This will save the time, money and resources of the organizations.

REFERENCES

1. http://www.fda.gov/downloads/Drugs/.../Guidances
2. http://www.pharmamanufacturing.com/articles/2009/129/
3. http://qualitymanagementsystem.com/what-is-iso/capa-quality-system-more-than-just-corrective-action/
4. fda.gov/downloads/RegulatoryInformation/Guidances/ucm128031.pdf
5. Guidance for Industry, fda.gov/.../2005-4136b1_05_pharmaceutical%20CGMP.pdf