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Conducting root cause analysis and its implementation: A perspective

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Perspective

Conducting root cause analysis and its implementation: A perspective

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Abstract

In the current widening global economy, failures can have profound impact on an organization's competitiveness. To be successful in business, every organization focuses on how to prevent failures in their manufactured products, processes, and operations. To reduce the loss, the only way out is to investigate their cause and prevent it from reoccurrence. Root cause analysis is an effective method to achieve this particular goal. Root cause analysis is a technique to address a non-conformance or problem to find out the real cause of particular problem. For investigation, various root cause analysis tools are used. The main aim of root cause analysis is to discover the actual cause of an observed problem, defect, or failure so as to utilize this particular information to correct it. After the investigation and identification of appropriate root cause the implementation of CAPA (Corrective Action and Preventive Action) should be done.

Keywords: Root Cause Analysis (RCA), Corrective Action and Preventive Action (CAPA), Investigation, RCA tools.

Introduction

In worldwide competitive markets, failures have been proved to be expensive and sometimes cause havoc to pharmaceutical organization. In order to be successful in business, every pharmaceutical organization focuses on how to prevent failures in their products or operations. A particular way to lessen the loss is to investigate their causes and prevent them from reoccurring.[1] Effective science-based investigations lead to error prevention, operational excellence and patient safety. It is a challenge to the industry, to apply appropriate scientific rigor to investigations. Pharmaceutical organizations that put in place meaningful failure investigations and processes for investigations will not only strengthen their business base but also achieve sustainable improvements in their productivity and product quality.[2]

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Root cause analysis

Root cause analysis (RCA) is performed to address a non-conformance or problem to get into actual cause of the problem. This method is used to either eliminate the cause or to prevent problem from reoccurring. Getting into the root of the cause means stopping that particular cause from ever happening again. Underlying causes are determined by using a structured problem solving approach. It avoids repetition of non-conformities; prevention of reoccurrences and provides permanent solutions. In some organizations it is a part of the policy and goal for facilitating improvement for a longer period and a strong vehicle for training people. Analyzing root cause depends on mind set and at the beginning it takes long period of time but is a high return investment for eliminating non-conformances.

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Root cause analysis is a technique which involves an application of a series of well known, common sense techniques which can produce and provide a systematic, documented and quantified approach to the identification, understanding and resolution of underlying causes. As mentioned below in the figure.[3]

Figure 1: Systematic steps for determining the underlying root cause

The fundamental principle of root cause analysis is to use symptoms as clues to find the source of a problem. Treating the symptoms can temporarily mask a problem or even make the problem worse.[4] The main aim of RCA is to find out the true or actual cause of an observed defect, failure, or problem and use that information to rectify it. As the root cause must be supported by evidence, the process for determining root cause is systematic and consistent. A combination of factors can contribute to a defect, failure or other problem. It is possible to identify probable root cause(s) for a given situation.[5] Analysis of root cause is a method which is developed to find out not only how an event occurred or what that event is, but also why it led the event to happen. Only when investigators are able to determine failure or event occurred then they will be able to specify appropriate corrective measures that can prevent future similar events to occur. The key to develop effective recommendations is only when an occurrence of the event is understood. Benefit of an effective RCA is that, the root causes identified over the time across the population of occurrences can be used to target major opportunities for improvement.

The RCA Process

1. **Data collection.** The basic step is to accumulate data related to the problem or event occurred. The root causes and casual factors related with the event cannot be identified without understanding and complete information of the problem or event occurred.

2. **Causal factor charting.** The causal factor chart is a flow diagram along with logic tests that explains the events from occurrence, along with the conditions surrounding these events. It facilitates a structure for investigators to organize and analyze the information accumulated during the investigation and to identify deficiencies and gaps in knowledge as the investigation progresses. The investigators are in a good position to identify the major contributors to the incident, called causal factors, once the entire occurrence has been charted out. Causal factors are those contributors (human errors and component failures) that, if eliminated, would have either reduced its severity or prevented the occurrence.

3. **Root cause identification.** Root cause identification. Investigators begin root cause identification after all the casual factors have been identified. In this step the underlying reason or reasons for each causal factor or factors are identified by the use of the decision diagram. With the help of decision diagram the reasoning process of investigators is understood and it also helps them by answering questions with regard to why the particular causal factors occur or exist.

4. **Recommendation generation and implementation.** The last step is the generation of recommendations. Achievable recommendations for preventing its reoccurrence are generated after identification of root causes for a particular casual factor. Organizations have to make sure that recommendations are tracked to completion.[6]

Merits of Comprehensive RCA

- Determining permanent solutions to the problem
- Prevent the failures from occurring again
- Introduction of logical problem solving process on all nonconformities.

There is no single method for conducting root cause analysis and any definite approach to identify the cause of the problem, many tools and methods are available for the analysis. The selection of methodology to determine cause of the problem is a matter of individual's selection or policy of company based on type of source of data or non-conformity being investigated. Whichever method of root cause analysis is used it is usually necessary to commence with, and record the known facts. Depending on the situation these may include:

- What is the non-conformity?
- When it was discovered and when it occurred?
- Any products/processes involved?
- Any immediate corrective action taken and completed?[7]

Flow diagram for conducting root cause analysis

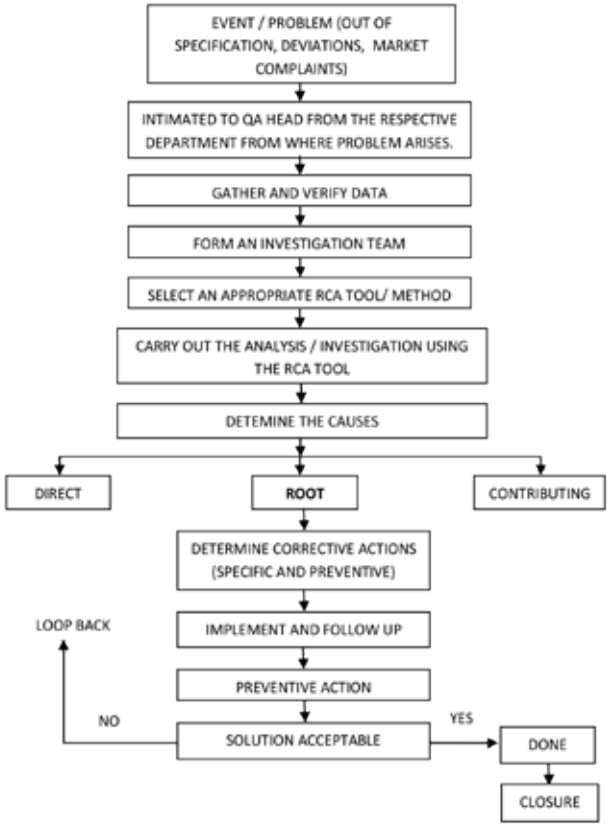

Figure 2: Systematic process for conducting root cause analysis

(Loop back means: If there is failure of the corrective action after implementation then the entire process should be repeated and studied thoroughly.)

Tools for root cause analysis

These are the tools to help and support the individuals or group of people to identify probable or appropriate root cause analysis. RCA tools must have the features to stimulate discussion, must be understandable and have mechanisms for evaluating integrity[8]

The Corrective Action and Preventive Action (CAPA): CAPA is the keystone for Quality Management System, especially backbone to Pharmaceutical Industry, and for quality improvements. CAPA helps the Quality System to upgrade firm, processes, stratagem, and business in an organized, well-documented and prosecutable manner. After achieving appropriate and true root cause the investigation is put to an end and implementation of CAPA is taken as the next step. CAPA is segregated into three different subjects:

I. Correction or Remedial Action,
II. Corrective Action (CA),
III. Preventive Action (PA)

Correction or remedial action

Correction or Remedial Action: Correction or remedial action emphasizes only on the immediate situation to eliminate an existing non-conformance or undesirable situation. It is essential to note that those actions that emphasize on the immediate situation do not tackle the root cause but just 'fixes' the problem temporarily.[9]

Corrective action

The term corrective action encompasses the process of responding to problems related to products or market complaints or any other defects and getting them corrected. This includes:

- Defining and reviewing the nonconformity or problem.
- Determining the reason of the defect or problem.
- Rectifying the problem by developing an action plan to prevent its occurrence.
- Getting the plan into action.
- Measuring the effectiveness of the correction.

The difference between correction or remedial and corrective action is that correction or remedial action is normally a repair service that is usually required to rectify an undesired condition because the system malfunctioned whereas corrective action is a form of system action that is performed after a problem emerges in a system with the goal of restoring operability to the system.

Preventive action

A process for determining actual problems or non- conformances and discarding them is called preventive action. This includes:

- To determine the actual cause of the defect or problem.
- To identify the reason of the actual problem.
- To develop a plan to prevent the occurrence.
- To get the plan implemented, and
- To review the effectiveness in preventing the problem and the actions taken.[10]

Importance of investigations

In order to adhere to the Food and Drug Administration, European or International organization for standardization regulations, an organization must undertake an investigation in the event of an unplanned deviation or any failures. An organization may define the nature of the investigation, but it must perform one as a compliance responsibility. Secondly, organizations also have an economic responsibility to investigate. Conducting an investigation and determining the root cause of an incident can be expensive, but well worth it if it can prevent future reoccurrence of similar deviations and failures considering that chronic problems can potentially hurt an organization in its market, especially if those problems result in any harm to consumers. Furthermore, health regulatory authorities have begun citing organizations in ever growing numbers for inadequate quality oversight. Thus, organizations must ensure that they apply appropriate quality oversight to all procedures. This will help to assure a high-quality product.[11]

Conclusion

Root cause analysis along with the corrective action and preventive action process are absolutely essential to improve the quality management system and to increase the quality of the final product. Conducting root cause analysis has become a basic requirement in every pharmaceutical industry due to global competition and need for the ultimate quality of the product or service. RCA is a process which helps in understanding and learning regarding the cause of failure or non-conformance. This process helps us to take and implement an effective CAPA so that the reoccurrence of the undesirable event can be prevented.

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