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Implementing Root Cause analysis in Pharmaceutical manufacturing

Maariyah Tahseen, Maleeha Masood, Trapti Saxena, Prasanthi Domaraju*

G. Pulla Reddy College of Pharmacy, Mehdipatnam, Hyderabad, - 500028 Telangana State, India.

Abstract

In every company failure can happen. It can have reflective impact on an organization's attractiveness. Every organization wants to achieve success in business, so, it focuses on the way to prevent let-downs in their processes. to stop the loss, to scale back the loss, the sole way out is to investigate their cause and prevent it from reoccurrence. Root cause analysis is an efficient method to achieve this particular goal. Root cause analysis may be a technique to address a non-conformance or problem to find out the real cause of particular problem. Various root cause analysis tools are used for investigation. The main aim of root cause analysis is to discover the actual cause of an observed problem, defect, or failure so to utilize this particular information to correct it. Subsequently, the search and identification of appropriate root cause should lead to the execution of CAPA (Corrective Action and Preventive Action).

Keywords: Root cause analysis, Steps of RCA, Benefits of RCA, Tools of root cause analysis, Ishikawa (Fishbone) Diagram

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*Corresponding author

1. Introduction

Root cause analysis (RCA) is performed to view a problem and to get into definite root of the problem. This method is used to either eradicate the cause or to prevent problem from reoccurring.

Getting into the root of the cause means discontinuing that cause from ever occurring again. It avoids replication of non-conformities; prevention of reoccurrences and provides permanent solutions. (1)

Analysing root cause depends on mind set and at the beginning it takes long period of time but is a high return speculation for abolishing non-conformances. (2)

Root cause analysis is a method which involves an claim of a series of well known, mutual sense methods which can provide an organized, documented and enumerated tactic to the identification, understanding and resolution of underlying sources. (3)

Corrective and preventive action consists of developments to an organization's processes taken to eradicate causes of non-conformities or other undesirable situations. It is usually a set of actions, laws or regulations required by an organization to take in manufacturing, documentation, procedures, or systems to correct and eradicate repeated non-conformance.

Corrective action: Action taken to eradicate the reasons of non-conformities or other undesirable situations, so as to prevent relapse.

Preventive action: Action taken to avoid the incidence of such non-conformities, generally as a result of a risk analysis. (4)

2. Steps for determining the underlying a root cause:

Step 1: Define the problem
Step 2: Collect data
Step 3: Identify casual factors
Step 4: Determine root cause analysis
Step 5: Implement solutions

a) Define the problem

A clearly defined problem is needed to perform a root cause analysis. If multiple problems are considered, it's best to start with one and accomplish multiple RCAs to find solutions for each. By attempting one problem at a time, it's a better chance of finding the cause of each subject and addressing it rapidly. While defining the problem it also encompasses getting everyone on the same page.

b) Collect your data

The second step includes collecting of evidence to support that the problem exists. Company research can

also be used to better comprehend the symptoms of the problem. Questions must be asked during this step.

c) Identify possible root causes

Identifying possible root causes is the most vital part of the root cause analysis process. The causes in this step will ultimately lead us towards a solution and action plan. Common problem-solving strategies include:

- Cause-and-effect flow chart: This flowchart splits down the problem into symptoms, possible causes, and actual causes in order to find a rational solution.
- 5 whys approach: The 5 whys approach can also be used to get into the root cause of a problem. Instead of taking the problem at face-value, ask "why" until you reveal a process or system that isn't working the way it's supposed to. When the first answer doesn't settle you land on, you can explore layers of issues that weren't conspicuous right away.

d) Determine the root cause

The determination of a root cause of a problem includes as many root causes as possible. Once every possibility is exhausted, the following questions can be asked:

- Are there any comparisons between the root causes that have been identified?
- Are there any explanations to eradicate any of these possible root causes?
- Which root cause seems most challenging?

The approaches used when observing for possible root causes, there are approaches to get into the actual root cause. These strategies include:

- Failure Mode and Effects Analysis (FMEA): FMEA is a tool similar to risk analysis where we will look at the possible root causes we have identified and eliminate the ones that are most likely to result in disaster later on.
- Impact analysis: Use an impact analysis to evaluate the positive and negative impacts of each possible root cause we have identified. Making a theoretical pro and cons list for each cause, we can feel more self-assured tapering down the list.

e) Implement solutions

The solutions you come up with should address the root cause, but as a result, these solutions will work their way back up the chain and address your initial problem.

Ask yourself these questions when developing solutions:

- How will we implement this solution if we choose it?
- What barriers will we be facing when executing this solution?
- How long will it take to execute this solution?
- Who will execute this solution?
- Could executing this explanation lead to other problems?

Once you're ready to generate the implementation plan, make sure it's shared in a tool that all participants can view. Project management software makes it easier for your team to collaborate and synchronize deliverables as needed. It may take several weeks to implement your plan, which means some of your aims may become dependent on other markers. Gantt charts are used to view project dependencies and cooperate in real-time.

The main intention of RCA is to find out the accurate or genuine cause of an observed fault, failure, or problem and use that information to fix it. As the root cause must be supported by indication, the process for determining root cause is organized and reliable.

Investigation of root cause is a technique which is developed to find out not only in what way an event happened or what that event is and why did the event happen.

The key to develop actual references is only when an incidence of the event is understood. Benefit of an effective RCA is that, the root causes recognized over the time across the population of occurrences can be used to target major chances for enhancement. (5)

3. Conduct of Root Cause Analysis

An efficacious root cause analysis recognizes all root causes-there is often more than one.

Consider the following instance:

A worker slips on a wet patch of water on the plant floor and falls. An outdated enquiry may find the cause to be "water spilled on the floor" with the remedy limited to cleaning up the spill and instructing the worker to be more careful. A root cause analysis would reveal that the water on the floor was purely a symptom of a more basic, or vital problem in the workplace. (6)

An employer conducting a root cause analysis to determine whether there are complete reasons for an occurrence should ask: –

- Why was the water on the floor in the first place?
- Were there variations in conditions, procedures, or the environment?
- What is the source of the water?
- What tasks were proceeding when the water was spilled?
- Why did the water remain on the floor?
- Why was it not cleaned up?
- How long had it been there?
- Was the spill reported?

It is significant to consider all possible "what," "why," and "how" questions to determine the root cause of an occurrence.

In this case, a root cause analysis may have exposed that the root cause of the spill was a failure to clean up the spill would not have prohibited future occurrences because there was no scheme to avoid, recognize, and accurate leaks.

4. Benefits of Root Cause Analysis for Employers

- Employers can avoid redundant costs resulting from business interruption, emergency response and clean-up, increased regulation, audits, inspections, and regulatory fines.
- Employers may find that they are expending money to correct instantaneous causes of incidents that could have been prohibited, or reduced in severity or frequency, by identifying and correcting the underlying system management failure.
- Finally, when an employer emphasises on prevention by using root cause analysis, public trust can be received.
- Employers with an incident free record may be more likely to appeal and recall high accomplishing staff. A vigorous process safety program, which includes root cause analysis, can also result in more operative control of threats, enhanced process consistency, amplified incomes, declined production costs, lower maintenance costs, and lower assurance payments. (7)

5. Tools of Root Cause Analysis

The following is a list of tools that may be utilised by employers to perform a root cause analysis. The tools are not meant to be used entirely. Preferably, a blend of tools will be used.

- Devising
- Checklists
- Sense/Event Trees
- Timelines
- Sequence Diagrams
- Causal Factor Identification

For simpler events, devising and checklists may be enough to identify causes of an event. For more complex events, sense/event trees should also be considered. Timelines, sequence diagrams, and causal factor identification are often used to support the sense/event tree tool. (8)

5.1. Ishikawa (Fishbone) Diagram

This is another tool created by Kaoru Ishikawa in 1968, for more compound difficulties are the Ishikawa diagrams (also known as fishbone diagrams, herringbone diagrams, cause-and-effect diagrams, or Fishikawa) are causal diagrams that show the causes of a specific occurrence. Each cause for inadequacy is a source of disparity.

The "5 Whys" can be used exclusively or with Ishikawa diagram. This method helps us discover all possible or factual causes that result in a single fault or disaster. Once all efforts are recognized on the fishbone, you can use the "5 Whys" methodology to drill down to the root causes.

Initially, to construct a fishbone, state the problem in the form of a question, for example,

"Why is process not free from impurities?" Bordering it as a "why" will help in devising, as each root cause idea should answer the question. The team should approve on the account of the problem and then place this question in a box at the "head" of the fishbone. (9)

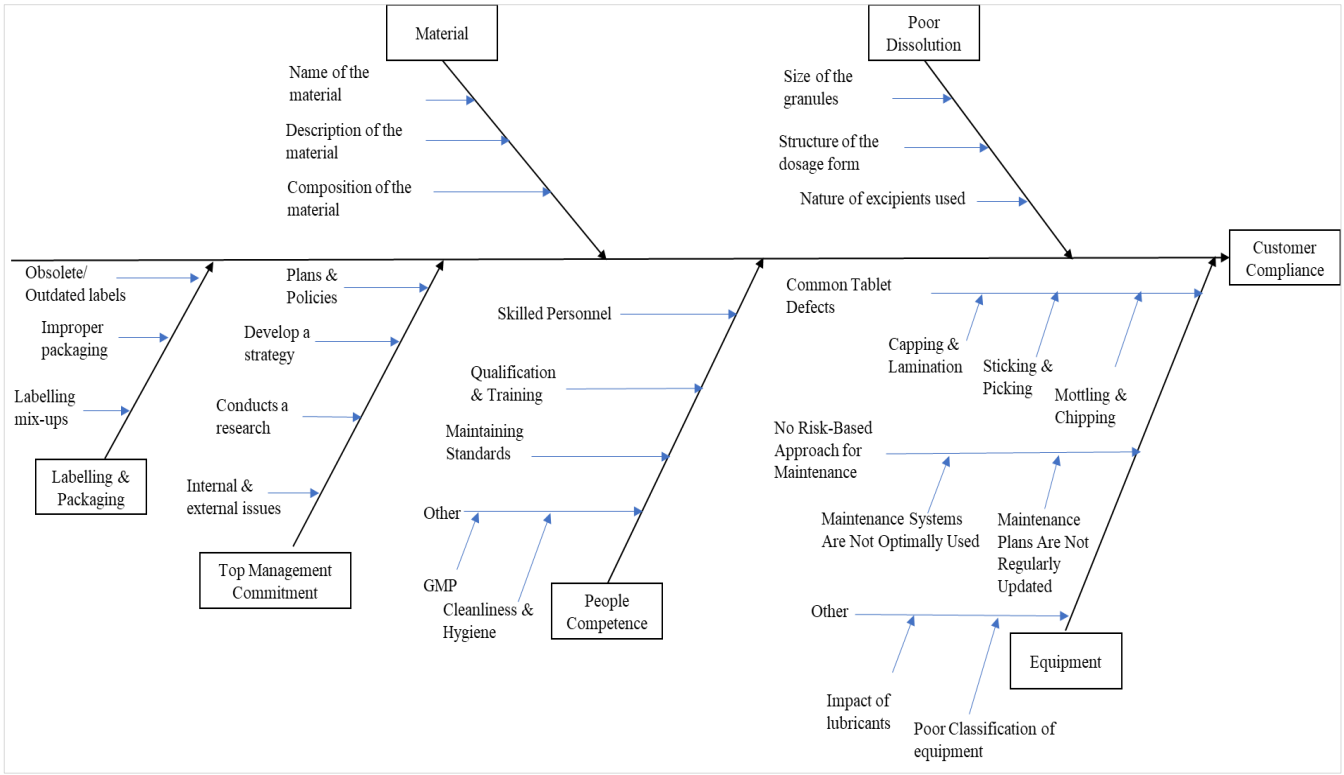

Figure 1. Fish Bone diagram for Customer compliance of the final Product (10)

The rest of the fishbone then consists of one main line drawn straight across the page (creating the spine),linked to the problem statement, and numerous lines or "bones" coming out straight up from the main line. These bones

signify categories of any factors contributing to the problem. For example, "Materials" could be one category (bone) with possible factors being raw materials and parts used to produce final product. (9)

The above given figure is a fish bone diagram for customer compliance for a tablet. It illustrates a risk assessment tool an Ishikawa (fish-bone) diagram that identifies potential variables which can have an impact on the final product with respect to its product characteristics. The RCA might be due to poor dissolution, material, equipment, personnel competence or it can be due to top management commitment and labelling and packaging of drugs. The reason for the root cause is best described in the above diagram.

5.2 Some other tools are

- Fault tree analysis (FTA)
- Hazard Analysis and Critical Control Points (HACCP)
- Failure mode effects analysis (FMEA)
- Failure mode, Effects and critically analysis (FMECA)
- Risk ranking and filtering
- Preliminary Hazard Analysis (PHA)
- Supporting statistical tools.

6. Conclusion

Root cause analysis is presently the highly preferable method in response to an adverse event and thus preventing the reoccurrence of the event. This method is widely used for reducing errors.

It has proven patient safety and it denotes an important qualitative tool that is complimentary to other techniques employed in error reduction. The use of RCA virtues more deliberation, as it offers a prescribed structure to study from previous blunders.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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