



ROOT CAUSE ANALYSIS (RCA) AND CORRECTIVE ACTION/IMPROVEMENT ACTION (CAIA) AS KEY TOOLS IN MANAGEMENT OF NON-CONFORMITIES

Adrijana Nosacheva Trajkovska¹, Natasa Kitanovska¹, Maja Poposka Stojchevska¹, Ornela Kuzmanovska¹, Elizabeta Karadzinska¹, Olivera Paneva¹

¹ Alkaloid AD, Skopje, R.N. Macedonia, anosacheva@alkaloid.com.mk, nkitanovska@alkaloid.com.mk, mpoposka@alkaloid.com.mk

Introduction & Aim

Introduction

The pharmaceutical industry operates under strict regulatory frameworks to ensure that medicinal products meet the highest standards of quality, safety, and efficacy of the products. Effective management of non-conformities in the pharmaceutical industry is essential for ensuring product quality, patient safety, and regulatory compliance. Nonconformity is any deviation from internal or external regulations / requirements applicable for pharmaceutical industry.

Based on Good Manufacturing Practice in the Pharmaceutical industry it is crucial to review all non-conformities, their investigation and implementation and following the effectiveness of corrective and improvement actions taken. This has fundamental importance for the maintaining product quality and regulatory compliance. While reporting of any nonconformity is mandatory, the key objective is identifying root causes and preventing recurrence. Root Cause Analysis (RCA) and Corrective and Improvement Actions (CAIA) are therefore fundamental elements of the pharmaceutical quality system as part of lifecycle management of the product as well as systems.

Aim

The aim of the study is to emphasize the importance of Root Cause Analysis and the Corrective and Improvement Actions (CAIA) taken as an essential tool for resolving non-conformities in pharmaceutical industry.

Methods

There are multiple root cause analysis tools, such as Ishikawa Fishbone Diagram, Pareto Chart, 5Why's, Fault Tree Analysis, Failure Mode and Effects Analysis (FMEA), Affinity Diagram, Scatter Plot, Variance Component Analysis (VCA) and Hypothesis testing.

This study focuses on the most common tools used in Alkaloid AD Skopje, Ishikawa Fishbone Diagram and 5Why's, as root cause analysis which are important and powerful methods for determination of root cause in the investigations and defining appropriate corrective actions.

Results and discussions

The most comprehensive and simple version of the Ishikawa Fishbone Diagram includes what are called the "6M categories": Man, Material, Method, Measurement, Machine and Mother Nature (Figure 1) The Ishikawa fishbone diagram is a cause/effect diagram used to explore all potential or real causes (inputs) that results in a single effect (output). Causes are arranged according to their level of importance resulting in an illustration of the relationships and hierarchy of events.

The 5 Why's quality tool (Figure 2) is used as a simplest yet most powerful methods for identifying the root cause of the nonconformity.

The pharmaceutical company should have a system for implementing Corrective and Improvement actions as a result of the investigations of complaints, product recalls, non-conformities, deviations, audits, regulatory inspections and findings, trends from process performance and product quality monitoring. Successfully implemented CAIA methodology results in product and process improvements. Effective Corrective action successfully-removes the root cause of the nonconformity and prevent the reoccurrence of the same non-conformity. A systematic investigation should be carried out to determine the reason(s) for the non-conformities, by using the root cause analysis and define appropriate corrective action.

Improvement action provides improvement of any process/product and also provide prevention of any potential occurrence of non-conformity by proactively implementing improvements and risk-based thinking. Based on the performed root cause identification, CA is implemented through clearly defined actions, tracking, and effectiveness verification (Figure 3).

The integration of RCA into CAIA process provides companies to determine root causes and through the implementation of effective CAIA to prevent recurrence in future, and strengthen process/product robustness.

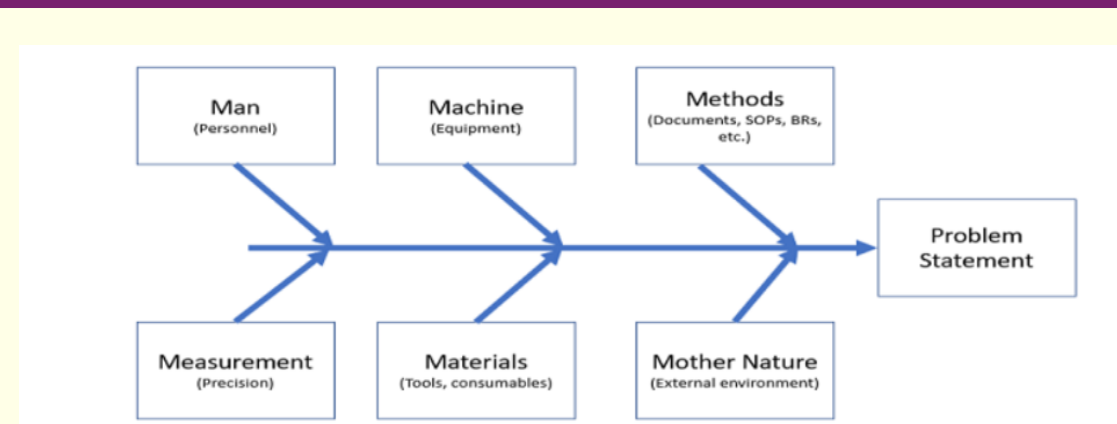


Figure 1. Illustration of Ishikawa Fishbone

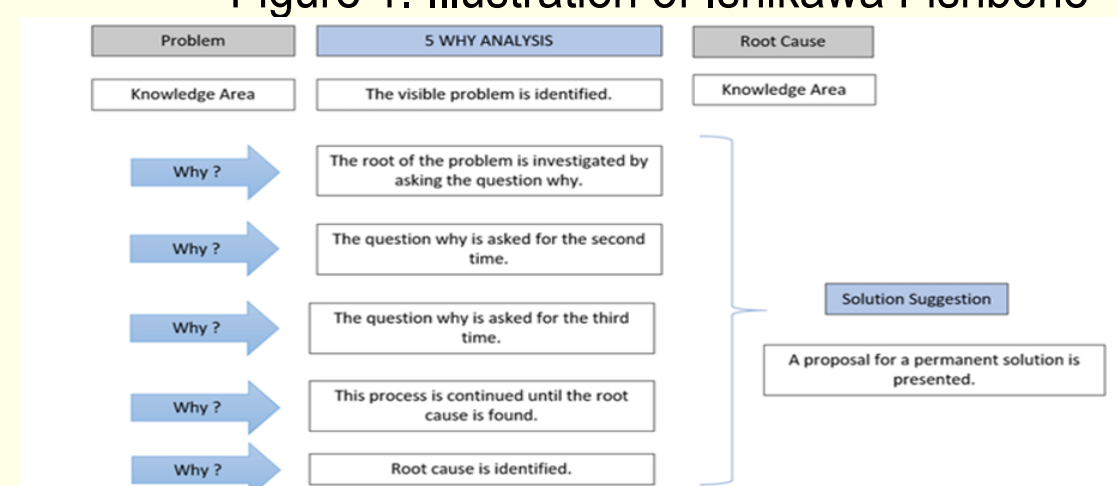


Figure 2. Illustration of 5 Whys 10

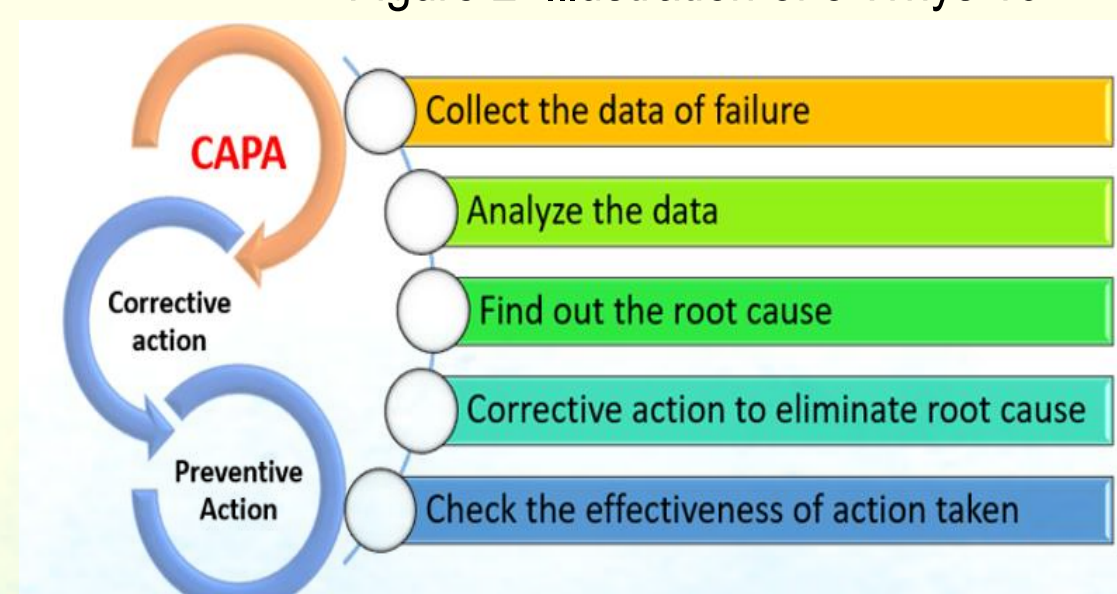


Figure 3. Illustration of the CAIA process

Conclusions

Effective management of non-conformities in the pharmaceutical industry is essential for ensuring product quality, patient safety, and regulatory compliance. RCA and CAIA represent essential tools for management of non-conformities in the pharmaceutical industry and preventing their recurrence.

An effective non-conformance management system is fundamental in the Pharmaceutical Quality System and plays a key role in ensuring the quality, safety and efficacy of pharmaceutical products. By establishing a structured and efficient non-conformance management process, the company can promptly recognize potential risks and prevent their negative impact on product quality and patient safety.

In the pharmaceutical industry, successfully managing the process of investigating non-conformities and defining of appropriate Corrective and Improvement actions (CAIA) is not only a regulatory requirement, but a strategic tool for ensuring quality, patient safety and continuous improvement of organizational performance.

Effective management of non-conformities, demonstrates the maturity of the quality system and the company's commitment to a culture of quality and continuous improvement and maintenance of the highest standards in pharmaceutical production.

