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Short communication

Root cause analysis as a critical element in the quality assurance strategy

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Introduction

Root Cause Analysis (RCA) is a structured, systematic problem-solving process used to identify the fundamental causes of quality issues within Integrated Management Systems (IMS), rather than addressing only their symptoms. In modern IMS, RCA is not only a reactive investigation process but also a proactive mechanism for continuous improvement.

This paper provides a general overview of RCA implementation in the IMS of Alkaloid AD Skopje, focusing on key tools, their strategic importance in QA decision-making, and their role in enabling proactive quality management and continuous improvement of the IMS.

Root Cause Analysis in the IMS

Within an IMS, RCA is primarily applied in the investigation of deviations, out-of-specification (OOS) results, complaints, audit findings, and process failures. It is closely integrated with CAIA systems and quality risk management processes.

An effective RCA process typically involves the clear definition of the nonconformity, systematic collection of relevant data, identification of potential causes, verification of root causes, and implementation of corrective and improvement actions.

Root Cause Analysis tools in IMS

5 Why's Method

The 5 Whys method is a simple but powerful tool used to identify the root cause by repeatedly asking "why" a problem occurred. It is particularly effective for straightforward investigations and is often applied during the initial stages of analysis.

Ishikawa Diagram (Fishbone diagram)

The Ishikawa diagram, also known as a cause-and-effect diagram (fishbone diagram) is a tool that helps users identify the many potential causes for a problem by sorting into groups such as equipment, process, personnel, materials, environment, and management. This tool is widely used in investigations to ensure comprehensive and systematic analysis and to avoid overlooking contributing factors. It is often applied in combination with the 5 Why's tool to support accurate identification of the root cause of a problem.

Failure Mode and Effects Analysis (FMEA)

FMEA is a risk-based approach used to identify potential failure modes in processes or systems before they occur, assess their impact, and prioritize them based on severity, probability, and detectability (Risk Priority Number – RPN). It is particularly valuable for proactive RCA during process design and optimization.

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Pareto Chart

Pareto Chart is a visual tool used to identify and prioritize the most significant problems within a dataset. The concept is rooted in the 80/20 rule, which suggests that 80% of results stem from only 20% of causes, such as defects in manufacturing processes. By addressing these high-impact causes, improvements become more effective and sustainable.

Role of RCA in QA decision-making

RCA plays a central role in supporting decision-making within the Quality Assurance strategy by enabling identification of the true causes of deviations, OOS results, complaints, audit findings, and process failures. This allows QA decisions to be based on objective evidence, which is particularly important in complex manufacturing environments.

The outcomes of RCA directly influence the effectiveness of corrective and improvement actions within IMS, ensuring that root causes are addressed, and recurrence is minimized. RCA also supports risk-based prioritization of quality issues based on their impact on product quality and patient safety.

In addition, RCA provides valuable input for trend analysis and performance monitoring, helping identify systemic weaknesses within the IMS and supporting strategic improvements. Therefore, RCA is not only an operational tool but also a key element in long-term QA strategy and regulatory compliance.

RCA as a tool for proactive IMS and continuous improvement

Although traditionally considered a reactive tool, RCA has evolved into a key driver of proactive IMS. When systematically applied, it enables identification of trends and recurring risks before they escalate into critical issues, supporting timely preventive actions and reducing deviations, OOS results, and other quality failures while improving process robustness and efficiency.

RCA is also a core element of continuous improvement within the IMS, as it identifies process gaps and supports targeted optimization, contributing to a strong quality culture based on evidence-based decision-making.

The integration of digital tools, such as eQMS and data analytics, further enhances RCA effectiveness by improving data visibility, traceability, and risk identification, supporting the transition toward more predictive, knowledge-driven quality management.

Conclusion

RCA represents a critical element of the Quality Assurance strategy. Its structured and systematic application enables accurate identification of underlying root causes of quality issues, supporting effective corrective and improvement actions and reducing the likelihood of recurrence.

Beyond its traditional role as a problem-solving tool, RCA contributes significantly to strategic QA decision-making and proactive IMS. It enables organizations to move from reactive responses toward predictive and improvement approaches, strengthening the overall effectiveness of the IMS. In the context of increasing regulatory expectations and ongoing digital transformation, the importance of RCA continues to grow. Its integration with modern analytical tools and data-driven systems will further enhance its role in continuous improvement processes. Ultimately, effective implementation of RCA supports sustainable quality performance, regulatory compliance, and the consistent delivery of high-quality, safe, and effective products.

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