NPG | Network Partners Group

ENHANCING CAPA THROUGH CONTINUOUS IMPROVEMENT

White paper for NPG's Quality COE | Written by Jeff Salerno and Eamon Salfi

INTRODUCTION

Life sciences companies are facing increasing pressure from regulatory bodies, to take a proactive approach to managing non-conformities, process deviations, and critical observations in relation to their defined quality procedures. Approximately 30% to 50% of all FDA-483 citations in FDA-regulated industries are related to problems with corrective action & preventive action (CAPA) processes. CAPA is one such process that has become a formal requirement by regulatory authorities for categorizing various issues a life sciences company may encounter. The DMAIC/CAPA system presented here is based on the define, measure, analyze, improve, and control (DMAIC) framework integrated within a CAPA system, which can enhance quality systems performance. The NPG DMAIC/CAPA framework is a business methodology that helps track down and mitigate the root causes of defects. Using the NPG DMAIC/CAPA system, you define a problem, measure the performance of an area or process, analyze the process, make improvements based on the analysis, and control the amended process. A DMAIC based CAPA system contains critical and key functionality, which individually and collectively must be used to properly manage all deviations or non-conformities while helping the company to manage, monitor and document its efforts to comply with FDA regulations as well as international regulatory authorities.

When thinking of CAPA, does Continuous Improvement (CI) come to mind? It may seem obvious that instituting a CAPA before or after an issue or deviation is discovered would result in improvement, since corrective action will address any current issues, and Preventive action will address similar future issues that could occur. If the CAPA is properly executed, then measures will be put in place to stop similar problems from occurring again. However, this doesn't extend to long-term improvements without further company-wide actions to ensure that the CAPA system is being utilized to facilitate Continuous Improvement.

NPG's DMAIC/CAPA integration can lead to long term Continuous Improvement and better implementation of critical CAPAs.

ENHANCING CAPA THROUGH CONTINUOUS IMPROVEMENT

Corrective and preventive actions (CAPA) are crucial organizational processes to identify and address issues effectively and efficiently. Implementing continuous improvement strategies such as the DMAIC framework in the CAPA process can lead to enhanced effectiveness and improved overall quality management.

Although CAPA is widely recognized, it shouldn't be something to utilize only after an audit or non-conformance report, but as an integral part of management systems. Thus, here are 4 general ways to use CAPA as a tool for continuous improvement.

1. Understand the root cause
When an irregularity or failure occurs, businesses can often make the error of dealing with the issue at hand instead of identifying the root cause of that issue. The problem with this is that the issue is often the consequence of a bigger systemic failure.

Treating the symptoms, rather than the cause of the irregularity itself, means that future issues are not avoided. Thus, the impact of the actions taken are short-lived.

CAPA promotes the identification of root causes, which is better for risk management. By doing this, the actions taken by the organization have long-term benefits as they can prevent irregularities from recurring. Thus, improving processes in the long run.

2. Create a risk-management culture
By getting everyone involved with CAPA, you can create a culture that views the resolution of mistakes and failures, lessons learned, and risk management as valuable parts of the workplace. A positive risk management culture is created and nurtured when a company is willing and prepared to accept that risks exist and is willing to address the risks discovered. Ultimately, this leads to more efficient and smarter responses to issues.

3. Drive employee productivity and quality
CAPA not only impacts how management deals with problems, but it also affects the behavior and response of employees. Through the promotion and institutionalization of corrective action and root cause analysis, employees can better identify flaws in both their work and in wider processes.

This way, employees contribute to continuous improvement, and thus, to better process quality.

4. Improve processes with Lean Six Sigma (LSS)
Lean Six Sigma (LSS) is a combined approach for improving organizational performance. Implementing CAPA strategies along with LSS, leads to better, faster, and more efficient organizational processes.

As such, integrating LSS principles with your CAPA processes can produce even better results.

ADDITIONAL BENEFITS OF CONTINUOUS IMPROVEMENT IN CAPA

- Enhanced problem-solving capabilities
- Greater efficiency in issue resolution
- Improved root cause analysis
- Increased compliance with regulatory requirements
- Enhanced customer satisfaction
- As the process follows a top-down approach, it allows equal participation as the process is easily understandable, irrespective of complex problems.
- The NPG DMAIC/CAPA method dictates analysis before implementation (Improve phase), thus reducing the chances of fixing the wrong issues or not addressing the issue at all.

Most importantly, the NPG DMAIC/CAPA method helps in building team coordination and communication. This directly affects overall completeness and effectiveness of CAPA initiatives.

STRATEGIES FOR IMPLEMENTING CONTINUOUS IMPROVEMENT IN CAPA

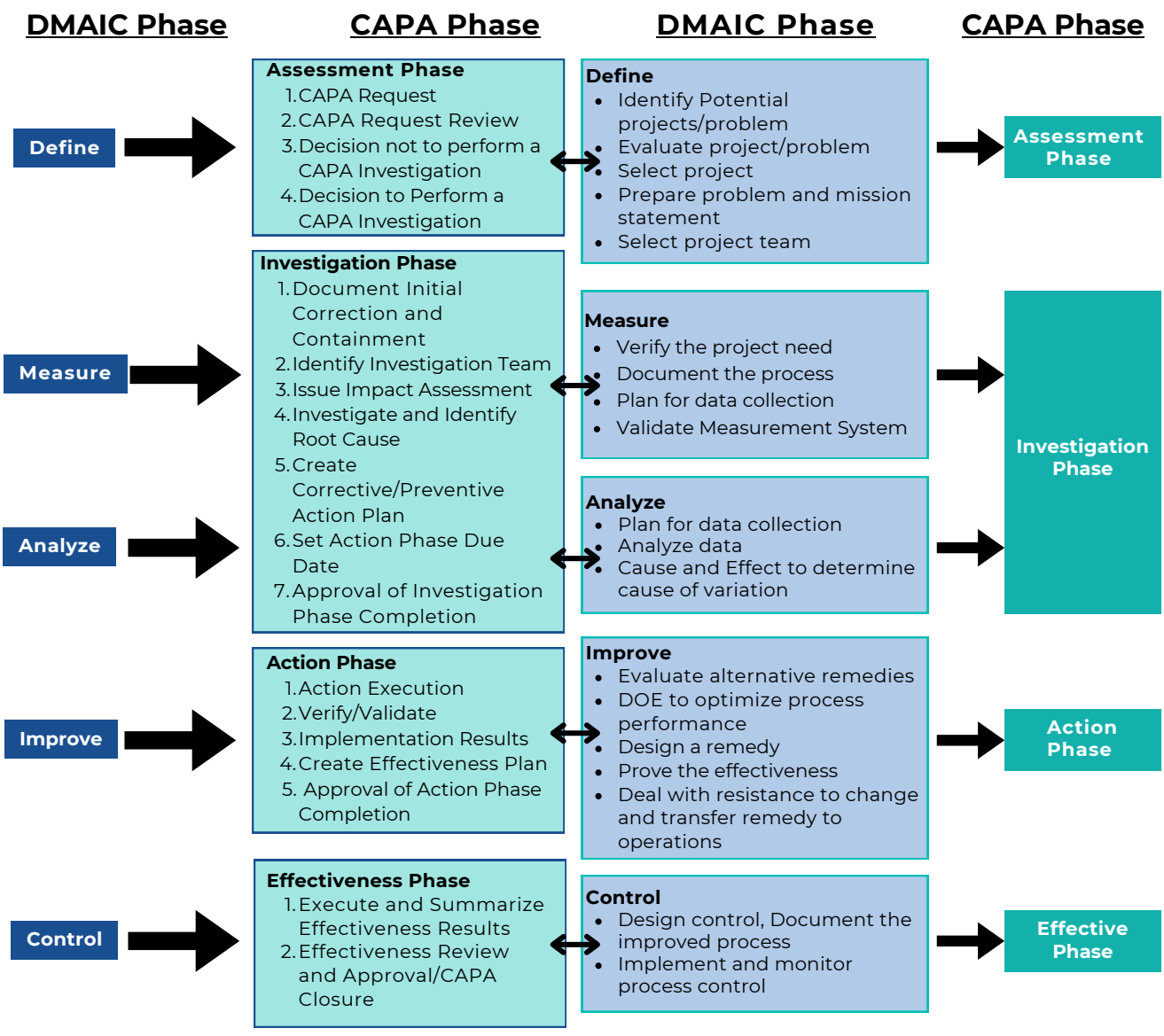
- **Regular Monitoring and Evaluation**: Conduct ongoing assessments of the CAPA process to identify areas for improvement.
- **Training and Skills Development**: Ensure that employees involved in the CAPA process receive adequate training to enhance their skills and problem-solving abilities.
- **Data-Driven Approach**: Utilize data analysis tools to identify trends, patterns, and opportunities for improvement within the CAPA process.
- **Cross-Functional Collaboration**: Encourage collaboration among different departments to gain diverse perspectives and insights for improving the CAPA process.
- **Continuous Review and Feedback**: Establish a system for continuous feedback and review of CAPA activities to drive improvement initiatives.
- **CAPA/DMAIC Integration**

WHAT IS CAPA AND DMAIC?

- **CAPA:** A systematic approach that includes actions needed to correct (correction), avoid recurrence (corrective action), and eliminate the cause of potential nonconforming product and other quality problems (preventive action).
- **DMAIC:** Methodology used for Six Sigma approach focusing on reducing variation in processes and preventing deficiencies in product, that involves five phases: define, measure, analyze, improve and, control.
- **Corrective Action**: An action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence.
- **Preventive Action:** Action to eliminate the cause of a potential non-conformity or other undesirable situation; 1. There can be more than one cause for a potential nonconformity, 2. Preventive action is taken to prevent occurrence.

CAPA AND DMAIC INTEGRATION METHODOLOGY

The methodology indicated is the key to getting effective and sustainable results. The CAPA process is applied/integrated with six sigma DMAIC methodology to identify the root cause of a problem. The CAPA process consists of four phases: (1) Assessment phase, (2) Investigation phase, (3) Action phase and (4) Effectiveness phase. The input process output (IPO) illustration below is a CAPA governance at a high level and six sigma methodologies under a systematic and structured process.



A higher dimensional level of checking effectiveness of CAPA is to implement DMAIC within the CAPA process. With DMAIC (define, measure, analyze, improve, and control) process, as outlined by Six Sigma, the CAPA process takes action to analyze and improve the processes of risk mitigation and objectively determines the effectiveness of the CAPA.

STATISTICS ON CONTINUOUS IMPROVEMENT IN CAPA

- According to a survey by a quality management organization, organizations that implement continuous improvement in CAPA experience a 20% increase in issue resolution efficiency.
- A study conducted by a regulatory agency revealed that companies with robust continuous improvement practices in CAPA are 30% more likely to achieve regulatory compliance.
- Research shows that companies that prioritize continuous improvement in CAPA witness a 15% improvement in customer satisfaction scores.

CONCLUSION

The application of Six Sigma methodology (DMAIC) to an existing CAPA process is the link to keeping sustainable gains when addressing quality issues. The validation of the primary contributors at the six sigma analyze phase is key to addressing the real causes of the condition within a quality issue. By integrating the DMAIC methodology within a CAPA generation, the possible root causes will be challenged, and proper controls will be implemented.

NPG's DMAIC/CAPA model follows a structured approach, which provides business with a road map for creating effective solutions. This helps organizations solve problems right from their roots. Moreover, NPG's DMAIC/CAPA methodology leverages an analytical approach, data, and other tools to make foolproof and data-driven corrections/changes.