

Leveraging Corrective and Preventive Action (CAPA) to  
enhance customer confidence



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## Increasing the need to be effective

In today's economy, pressures to compete have never been higher. Leaders are constantly searching for ways to make their organizations more effective while maintaining or improving worker safety.

One often overlooked approach is through the implementation of tools and techniques to resolve problems, from asset / product design to the manufacturing floor to the warehouse to after sales service. The Corrective Actions Preventive Actions (CAPAs) process is driven by the Root Cause Analysis (RCA) process within the overall business process.

Time after time with our clients, we find it is focusing on the fundamentals that enable waste reduction through the disciplined approach of root cause analysis (RCA).

- The methodology and process are crucial to continuous improvement
- RCA is typically not used effectively to solve issues in most organization.
- Leaders should be more involved in CAPA process to monitor and drive improvement.

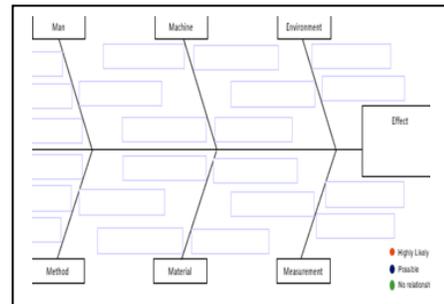
## Following the Methodology and process is critical

The overall process of problem solving has many different variants and formats across all industries. However, the general process and its execution flow are typically the same. The process involves clearly defining the problem, identifying the contributing causes and location of the problem, determining the root cause or causes and correcting for those.

From our work with clients, we have found that following these process steps effectively solves problems:

1. Initial perception / understanding and clarify the problem and magnitude
2. Determine where exactly in the process the problem is occurring
3. Implement containment(s) solutions
4. Conduct a brainstorming session of potential causes

5. Conduct Cause Analysis, i.e. what are the direct and contributing causes
6. Perform Root Cause Analysis, using tools such as 5-Why or Fishbone
7. Define countermeasures and corrective actions
8. Complete corrective actions
9. Verify effectiveness of actions taken
10. Communicate and share learning



### Effectively using RCA to solve issues

Properly defining the problem is the most important and first step. Recognize that there is a problem in the first place and decide whether the problem is big enough to warrant investing in a full root cause analysis (RCA). Prioritization tools including a weighing effort and impact, will help in the decision process.

Root Cause Analysis done correctly requires cross-functional collaboration, however the resources required will vary for each problem. Without upfront determination and the pre-planning, the organization will get overwhelmed leading to rushed or stalled RCA's and risk that the problem will recur and cause ongoing issues.

Most problem-solving efforts are influenced by assumptions. With mounting performance pressure many people favor skipping a deep dive and moving right on to the perceived solution. This risks recurrence or solving the wrong problem and setting up for failure. Effort needs to be spent in answering "Who", "What", "Where", "When", "Why" and "How" to fully understand and clarify the problem.

The next part of effectively solving a problem is to look deeper than the surface. As an example, if an electrical fuse blew or circuit breaker tripped, simply replacing the fuse or resetting the breaker would certainly restore power, but if nothing is changed in the power load, most likely the fuse will blow or breaker trip again causing further losses in production. The failure is a signal that there is something overloading the system beyond the rated capacity. Effective RCA can help define the reason of the problem, which is contributing to the blown fuse or tripped breaker. The same applies to all processes. Initial observation may be a symptom and not the true cause. Therefore, finding the cause is the start of defining the problem.

To fully define the problem, there is a need to go beyond assumptions, i.e. speak with the data and live evidence.

- Thoroughly review data and evidence

- Interview Operators
- Walk the process

Every cause needs a 5-Why / Root Cause. Many problems may have more than one cause. It is a common pitfall that a single cause is brought forth and explored. Analysis should be performed on each cause identified. Robust corrective actions to ensure effectiveness should be derived using a Hierarchy of Controls. The best controls ensure the problem will never happen again. For example, poke yoke and engineering redesign would be more robust than sending a memo or talking to an employee about a common mistake.

### **Leaders should be involved in CAPA process**

In some industries regulations drive the need to stay on top of CAPAs. For others, customer expectations including service level agreements (SLA), may be the reason. Regardless, it's always a good operating practice to drive and manage CAPAs, both to meet the Quality Management System requirements and to ensure efficient operations.

Visibility and support of leadership therefore plays a critical role to demonstrate to employees that the leadership is committed to effectively implementing Corrective Actions Preventive Actions (CAPA).

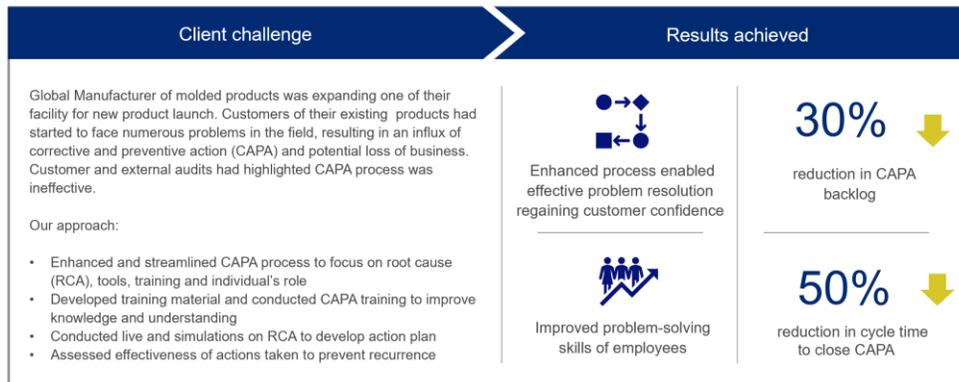
An outcome of RCA may require additional training, or capital expenditure. Ensuring and providing resources to solve problems is an important demonstration of leaderships commitment. Making this visible and prioritizing also exhibits leadership commitment to closing CAPA.

So, in practical sense, Leadership must be involved throughout the CAPA process and provide the platform that enables frequent (daily or weekly or monthly) review of the progress to understand the root cause and take actions.

Ultimately their visible commitment helps build the culture of their organization.

Case study below highlights how we have supported clients to implement this tool effectively.

## Effective CAPA process supported site readiness: case overview



### About the authors:

Rajeev Dureja is a Partner with X/Celerant, he has been consulting clients across manufacturing, chemicals, metals & mining industry in US, Canada and Europe. He collaborates with clients to create value through focus on execution & implementation leading to sustained results. He focuses on Operational Readiness, O&M optimization, Asset Management, Procurement and Supplier Development. He can be reached at [rajeev.dureja@xcelerantconsulting.com](mailto:rajeev.dureja@xcelerantconsulting.com)

Jeff Sanders is a Director at X/Celerant, he has been leading several performance improvements and restructuring initiatives with Fortune 500 companies. He has extensive hands on experience in business process design, cost/operational efficiencies, planning and integrated scheduling. Jeff can be reached at [jeff.sanders@xcelerantconsulting.com](mailto:jeff.sanders@xcelerantconsulting.com)

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