# Practical Tips to Eliminate Quickly CAPAs Backlog

**By Alec Alpert**


While on CAPA remediation projects as a CAPA Coordinator with the task of reducing or eliminating severe backlogs as fast as possible, I came up with ways of improving CAPAs' time to closure that I would like to share with you in this article.

Everything begins with the CAPA process. Although each company has its own CAPA policies and procedures, the basic steps in CAPA processing are common throughout the industry. They include:

**Step 1 – CAPA Trigger.** The trigger criteria for issuing a CAPA are based on the analysis of quality data, which can be nonconforming material reports (NCRs), product deviations, scrap, repairs, equipment calibration, audits, product complaints, supplier reports, recall activities, post-market surveillance, personnel training, work operations, quality records, and management reviews.

**Step 2 – Containment/Correction.** In this step, containment and/or corrections take place to address the nonconformance. Then an investigation plan and its completion date are determined.

**Step 3 – Investigation/Root Cause Analysis.** This step involves determination of the root-cause(s) of nonconformity by:

- Collecting and analyzing historical data.

- Using root-cause analysis tools, such as Is/Is Not, 5 Whys, Pareto, Fishbone, DMAIC, etc.
- Performing risk assessment.

**Step 4 – Action Plan.** After the root-cause(s) have been determined, a step-by-step action plan for correcting and preventing recurrence of nonconformance is developed.

**Step 5 – Action Plan Implementation.** In this step, individual tasks of the Action Plan are implemented.

**Step 6 – Verification of Effectiveness (VoE).** This step verifies that the corrective and preventive actions are indeed effective, and that the VoE acceptance criterion set forth by the VoE Plan has been met. This is the most time-consuming step because it requires collecting a statistically significant amount of data for making a VoE pass/fail decision.

The six steps above are a bare-bones outline of the CAPA process, and of course there is much more to it, as addressed in companies' CAPA procedures.

Usually, the goal is to complete these six steps within three to six months, which in real life is not always achieved for various reasons, thus creating backlogs. When a severe backlog in CAPAs occurs, CAPA remediation projects are initiated to gain control of the situation and reduce or eliminate that backlog. Large-scale and sophisticated manufacturing processes with thousands of pieces of equipment and multiple production lines seem to produce a steady flow of CAPAs.

As I've mentioned earlier, I've been on such CAPA remediation projects, and one of my observations was that CAPAs were not necessarily treated as engineering projects, which they are.

Once I started treating CAPAs assigned to me as important engineering projects that were like any other engineering projects, and ensured this paradigm shift occurred with others, a noticeable improvement in CAPA processing speed began emerging quickly. According to feedback from engineers, they started getting better appreciation and more credit for their CAPA efforts (i.e., productivity improved).

Another improvement was that I established weekly, face-to-face, hour-long meetings with each CAPA Owner to do an in-depth overview of the CAPA tasks and try to understand and resolve bottlenecks. All meetings were followed by immediate publication of the meeting minutes, with distribution to senior management.

I published those meeting minutes as a formal Word document attached to emails, which included key items such as:

- CAPA number
- Meeting date
- Who attended the meeting
- Executive summary of issues discussed
- Individual tasks' completion status, due dates, persons responsible, and pressing issues.

Meeting minutes identified immediate issues that were slowing down CAPA processing, making those issues evident. This visibility, in fact, made a big difference, resulting in offerings of additional resources from the CAPA Committee, valuable comments from management, and shifting CAPAs' priority to a higher level among other projects that CAPA Owners handled.

In addition to the meeting minutes, we maintained Microsoft Project Gantt charts, with all CAPA individual tasks and subtasks listed and due dates assigned and tracked.

Moreover, I completely took on the responsibility for revising and updating assigned CAPAs in real time in the CAPA electronic database to ensure their full compliance with Good Documentation Practices (GDP); the use of proper, professional English; adherence to procedures and regulations; and the presence and correctness of all attachments. This ensured that CAPAs were in regulatory compliance and audit-ready, and it added extra time for CAPA Owners to work on resolving the issues.

As a result, good communication, cooperation, and, most important, enhanced dedication, accountability, and enthusiasm were established and maintained among the personnel involved, leading to a noticeable acceleration in CAPAs processing. All in all, the backlogs were successfully resolved in a timely fashion!

**About the Author**

Alec Alpert is a Quality Engineer and Consultant with an extensive background in quality and compliance for medical devices from new product development, to operations, to post-market activities. He has helped to improve product quality and compliance at the leading medical device companies in applications ranging from linear accelerators, anesthesia systems, and implantable orthopedic devices to electronic imaging systems, infectious disease diagnostic systems, and electrosurgical generators. Alec is the owner of Alpert Engineering, LLC, an engineering consulting company that provides services to medical device companies. Alec is also the owner of www.alecalpert.com, where he publishes articles and white papers with practical advice on medical device technology, quality assurance, and compliance.