

COMPUTER ASSISTED CAPA

Corrective and Preventive Actions

Let's summarize the principles of a good CAPA system. It's really quite simple:

1. The first principle is to keep non-conformances (nc's) and capa separate. There is a reason why they have been kept separate in ISO 9001 (8.3 and 8.5). With nc's, we are solving (dispositioning) problems with the product and service that we are providing. With capa, we are solving problems with the process(es) that produce the product. Among several reasons for keeping them separate is that dispositioning every single nc is a must. CAPA, on the other hand, is discretionary, and depends on the severity of the nc. Some large customers give vendors forms that combine the two. What they are implying is that they consider the problem identified as serious enough to prevent in the future; and therefore they require both dispositioning and corrective actions.
2. The second principle is that there must be a high level of discipline in handling nc's as well as capa's. In the heat of battle in most business environments, the temptation to cut corners can be strong, and sometimes leads to costly errors.
3. The third principle is that records must be kept. This may sound bureaucratic, but there is a very good systems reason for disciplined record keeping. The reason is that good and detailed records provide data, and the intelligence upon which to make informed and smart decisions.
4. The fourth principle is that the system must be simple to use, so that people will use it, and use it faithfully. This is what will make the system really effective.

The above is all very well and good. The problem is that principle number 4, the secret to effectiveness, goes against principles number 1, 2, and 3. The good news is that there could be a solution. That solution is to use a computer assisted system. We need the power of the computer to eliminate the paper-work, the bureaucracy and the drudgery. This can be done by analyzing quality processes into two components—the necessary overhead, and the value adding component. Let's have the computer do the overhead piece, and smart humans do the value adding piece. A good computer assisted system will follow the work-flow required of a good Quality Management System (QMS), and ensure through a system of alerts, reminders and escalations. It will also ensure that all required steps are completed in a systematic manner, with proper vetting, and then finally keep records. The computer assistance will also make the job of analysis of all relevant data much simpler, faster, and therefore most likely to be done right. The following are typical steps taken for the sake of doing a good CAPA with an eye on compliance, **without** a computer based (electronic) system:

1. Reporting Recurring Nonconforming Products/processes in CAPA form, filling out the CAPA form.
2. Printing out at least 2 copies for Supervisor/Quality manager to review and a self copy
3. Using the company interoffice mail, e-mail or walk it to the supervisors.
4. Supervisors QM Approves/rejects CAPA based on merit and sign off on the approved CAPA form.
5. Notify personnel if CAPA is not approved.
6. Print a copy and send it to the someone to do the Root Cause Evaluation through company mail or walking.
7. Assigned personnel reviews the CAPA and write their finding and propose Action(s) and send it back to QM through company mail or walking.
8. Supervisors/ QM Approves/rejects the finding of the CAPA based on merit and sign off on the approved CAPA form.
9. If rejected, send it back to the Assigned person to do it again.
10. If approved, print another copy, assign someone to do the implementation of the proposed plan to stop recurrence/ occurrence of the Problem.
11. Assigned personnel reviews the CAPA, Implement the process and write implementation notes once completed and send it back to QM thru company mail/ e-mail or walking.
12. Supervisors/ QM approves/rejects the implementation of the CAPA based on merit and sign off on the approved CAPA form.
13. If rejected, send it back to the Assigned person to do it again.
14. If approved, print another copy, assign someone to do the verification of the Implementation to see effectiveness.
15. Assigned personnel reviews the CAPA, conduct the verification based on implementation notes and send it back to QM thru company mail or walking.
16. QM finally closes the CAPA and Notify the Originating Person.
17. Enter data into an excel or some other data base so as to be able to monitor the effectiveness of the CAPA system, and look for further opportunities for continual improvement.

The steps shown above are typical of a small-medium sized manufacturing company with a combination paper/ electronic system. For the sake of estimating the increase in efficiency of personnel, use the single asterisks to estimate that the time taken will be reduced to half. Those with double asterisks will be eliminated entirely.

But, the big benefit is in having a system that is much more effective!! The benefit of that is of course, priceless!

To see such a solution, click on the following link, and see at least presentations # 1 and #3.

http://www.qisssoftware.com/qiss_demo_presentations.asp

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